Health Resources and Services Administration
Negotiated Rulemaking
Designation of Medically Underserved Areas/Populations & Health Professional Shortage Areas

DRAFT COMMITTEE MEETING MINUTES

October 12-13, 2011

The Negotiated Rulemaking Committee (hereafter the "Committee") was convened for its fourteenth meeting at 9:40 AM on October 12, 2011 at the Sheraton Suites in Alexandria, VA. The meeting was facilitated by Lynn Sylvester and Dan LeClair of the Federal Mediation and Conciliation Service.

Committee members participating:

Andrea Brassard
Roy Brooks
Jose Camacho
Kathleen Clanon
Daniel Hawkins
Sherry Hirota
Steve Holloway
Barbara Kornblau
Tess Kuenning
Alice Larson
Timothy McBride
Lolita McDavid
Alan Morgan
Gail Nickerson
Charles Owens
Robert Phillips
Alice Rarig
Edward Salsberg
William Scanlon
H. Sally Smith
Donald Taylor
Christopher Vaz – alternate for John Supplitt

WELCOME AND SUMMARY

Ms. Sylvester opened the meeting. Dr. Taylor, Mr. Camacho, and Ms. Brassard joined the Committee by phone. She urged the group to work cooperatively with one another and reminded them of the alternative if a consensus is not reached-HRSA/HHS will develop a rule themselves.

He reminded the group that the vote on the report would be at 3 and 4PM tomorrow and that the vote should be on the big picture rather than line by line comments. Mr. Salsberg introduced Dr. Jan Heinrich, the Associate Administrator for the Bureau of Health Professions at HRSA, who thanked the Committee for their hard work into looking at new approaches for shortage designations.

Mr. Salsberg outlined the process for the meeting as well as Committee status and what happens after the report is filed with the Secretary. He noted that the Committee has been provided with additional information outlining the impact for geographic HPSAs and MUAs, which reflects the summary impact statement.

Mr. Salsberg discussed the five-page high level summary of the Committee's agreements as well as the draft report that Jessica Sitko of HRSA put together. He recommended that they vote on individual sections as the Committee worked and to leave the final vote on Thursday for the full package. He further recommended that any member of the Committee that would like to have a vote for the record on any provision ask for that vote. Mr. Salsberg reiterated Dr. Goodman's point that full consensus may not be the only value of the Committee's work given the high number of Committee members and its diversity, and that the most valuable product of the Committee remains the record of considerations and analysis. Without consensus, HRSA will likely reach a rule that would be reasonably close to the Committee's deliberations, with input from other federal agencies.

Mr. Salsberg stressed that HRSA would be likely to move forward with the recommendations, with or without consensus. He read from the Federal Register Notice regarding the Committee's establishment that if the Committee does not reach consensus on the proposed rule they may submit a report with areas where consensus was achieved, as well as any other information recommendations or materials considered appropriate. Any Committee member may include as an addendum their own recommendations. Mr. Salsberg noted the importance of the individual votes on record: that full consensus on individual items may weigh on final decisions of the Secretary. The final decision on the package is also a critical decision and he reminded them of the definition of consensus – if 70% comfortable vote 100% for the full package. Mr. Salsberg noted his personal experience with losing out on provisions and still being able to support the full package and asked that the Committee keep in mind that the goal is not perfection.

Mr. Salsberg explained the work that HRSA staff will do over the following three weeks. He noted that HRSA will do their best to put down on paper exactly what the Committee has decided, but there are some areas where the debate has been fuzzy which might require clarification. Once the report goes to the Secretary, others in Federal government will have the opportunity to comment on proposed regulation. Once the regulation is in draft no outside discussions are allowed.

COMMITTEE MEMBERS RESPOND TO CONSENSUS HOPES

Mr. Brooks felt that the most important outcome is consensus from the group; that is what we all came here for.

Dr. Larson agreed with Mr. Brooks and reminded the group that if consensus is not reached, HRSA can do whatever they want and that Committee members (and their respective organizations) are no longer bound as they would have been otherwise. Mr. Salsberg noted that the Administrative Procedures Act limits HHS from having any consultation with outside groups once a draft rule is under formal review.

Mr. Hawkins agreed with Mr. Brooks and reminded the Committee that the ground rules state that it can identify areas of agreement and disagreement, and members can comment on areas of disagreement. Mr. Hawkins noted that the Department has limited flexibility not to publish the consensus of the Committees an interim final rule making unless it is inconsistent with the statute or for other legal rules. In other words, he believes OMB does not have the authority to change a consensus recommendation. There's a huge difference between one or two dissenting votes and full consensus, and there is no agreement that allows for a minority report. Mr. Hawkins asked whether or not the definition of consensus could be changed. He would like to avoid that but if folks feel strongly that they can't go along with this final report, perhaps that would be an option. He pointed out that, for example, while he fundamentally disagrees with limitations the Committee agreed upon regarding the geographic HPSA designation threshold, for the sake of unity he will not oppose the final report on that issue.

Mr. LeClair clarified that the Committee's aim since last August was for 100% consensus. Mr. Hawkins clarified that that was his biggest goal also. Ms. Kuenning agreed with 100% as the goal, and asked whether someone could abstain from a vote even though they're present, and whether or not an abstaining vote could write a minority opinion.

Mr. Salsberg recommended taking on the two issues of greatest concern and addressing them directly, which might then make it easier to get through the substantive discussion. Those two issues include; first, Dr. Scanlon's email expressing concern that the Committee did not effectively target federal resources and that the proposed designations we include too many people which will result in the resources not being targeted and potentially additional federal expenses and second:, the additional analysis done by JSI of the population designation and concern that the proposed MUPs model for low income groups could result in 93% of the RSAs being designated as eligible for population designation for low income. So, there is concern that it's too open. Mr. Salsberg commented that this was not inconsistent with Bill's concerns but for a very specific piece of the report. Mr. Salsberg asked whether there were any other substantive fall on their sword issues for the Committee.

Mr. Camacho expressed concern regarding the concept of instructing HRSA. He felt that the Committee could include in its report a recommendation urging HRSA to target in their resource allocation functions to the highest need communities and urge them to consider using the methodology in part developed

by the Committee. He thought it might help assure those concerned that the Committee has not done enough on the targeting side.

Dr. Scanlon spoke with regard to the email he sent after the last Committee meeting. He said that he had been trying to tell the Committee his stance from the outset and in either May or June warned folks that he may not vote for consensus. There is a huge difference between individual elements and the whole package. There is a question that that when all the individual elements are put together they do not lead to total satisfaction. He was anticipating whether or not he could support the package in its totality. He has no stake in this other than the public good, and receives no money nor increase of knowledge base for working on the Committee. He understands the desire to reach consensus, especially as he is very involved in policy and policy making. He also knows the impact of bad policy and the difficulties of change, of which the current rule is an example. Dr. Scanlon is worried about putting the rule into place given the difficulty of change as well as the vagueness of the rule. The government could lose billions of dollars again because of these vague policies. HRSA will be the arbitrator/judge in terms of allocating resources most efficiently/effectively. He realizes that rules/regulations are not just an attempt to make sure that the agency faithfully follows the statute; they're also a protection for the agency. Agencies are bombarded by special interests, and for them to resist is not always possible. It's not that the government is bad or lazy; it's putting the agency in an untenable position of not being able to do what's best from a social perspective. The rules are a very important tool for the agency to be able to say what they can and cannot do. It is very important for the rule to be as clear and as well-defined as possible.

Dr. Scanlon went on to discuss the process of the Committee. He thought it had done a great job and made the work seem very cohesive and logical, although to him it seemed to exaggerate the evidence base for some of the proposed rule. There was a lot of information given to the Committee over the past few months, but it was in many fragments and no analytical whole. He felt the group never got to the kind of analysis that he felt is much more typical of policy making. He felt that the idea that we were going to use evidence and have an empirical basis seemed to get thrown out of the window around August when the Committee realized time was running short. Many of the items he felt were ad hoc: an example he cited MUA weights. He felt that a validly specified factor analysis was never presented, and in fact in some cases they were told Factor analysis was not valid in certain circumstances but it was used as a rationale for decisions anyway.

Dr. Scanlon felt that JSI had done a remarkable job pulling together the information for the impact analysis. and could appreciate it given his work in other arenas; JSI likely had to work late, painstaking hours. He felt that the factor analysis was great but as a start, and was not the real analysis needed to determine what the recommendations would mean. The Committee would need to be able to break down the aggregate impact to learn what the impact is on the sub-groups in order for him to be fully comfortable with the recommendations the Committee proposes.

Regarding GEO HPSAs, specifically, Dr. Scanlon felt that the definition of need is not just a function of numbers but effected by the construction of the Committee, and while he could live with the weights, the thresholds bother him. The thresholds and the curve were partially designed to avoid spending more

Medicare money but he worries about increasing the numbers covered; the Committee has included a footnote that says more areas will probably be covered when people submit l data and locally defined RSAs. But, the Committee does not know how many more areas will be covered, or the impact of increased coverage. The idea of the Medicare incentive money is to get people to go to the places that need services. When the area is spread wide, there are many options for people to go to and they will not go to the neediests areas.

Dr. Scanlon also specifically worried about the impact of the individual decisions that have been made and felt that the full impact of these had not been figured out given the number of moving parts. Thresholds, weights, back outs, inclusion of NP/PAs, modification for frontier areas – these are s options that the Committee maybe should have considered much earlier and much more deeply since a single threshold/calculation may not be appropriate. Regarding MUAs, Dr. Scanlon did not think the Committee had a sound framework for the MUA designations – but stayed with an index model without exploring options. Instead. Under service or shortage, which as phrases imply there is not enough, should not be added together with the other factors-adding P2P to the poverty measure and other measures does not give an index of shortage or under service but instead a number which has in some respects no conceptual meaning. The Committee needs to consider something similar to HPSAs in terms of trying to define shortage. Dr. Scanlon did not think that the notion of 33% of the population as underserved was tenable to the general population or good policy. Poverty is not a guaranteed indicator that a person needs more health care services but a result of many factors Dr. Scanlon felt that it was a disservice to assume those in poverty necessarily need more health care. In terms of the economy, health care is starting to crowd out education, housing support, food support, etc. and we have ignored what we are doing for poor people that might help them more than health care. Some states make a much bigger effort in the area of health care too, and to ignore it is very problematic.

Dr. Scanlon was also worried about the data. He felt the Committee relied a great deal on the notion that there is no good data source so either the Committee will patch together or use locally collected data. It's hard to collect data. The standards that the federal government uses for release of information are really quite high and if compared to the private sector or local sources those other sources would never come close to meeting the standard. NCHS has about 60 or 70% threshold for response rates before it will release. The AMA is lucky if it has 10%. Response bias is a concern.

Unless there are dramatic changes Dr. Scanlon told the Committee he would vote no on the package. One of the reasons for that is that he thinks the work is not done. He thinks it's a good thing if the Committee gives HRSA what has been done and tells them they need to continue the analysis before they develop those rules. That means that Committee members can comment but HRSA should not worry if they feel that they can defend the rule. He felt the current proposal could be attacked as inappropriate and arbitrary.

Dr. Scanlon concluded that he invested just as much time as the rest of the Committee, but it's not the worst of all worlds for HRSA to be charged to continue the work that we have now.

Dr. Rarig spoke to respond to Dr. Scanlon but first brought up several points. The first was that she felt that the Committee felt very challenged by the fact that there's this expectation that in 14 months they could undertake as massive a charge as this is given the consequences nationally and given the fact that they didn't have the luxury of developing all of the evidence that they might wish to rely on. The Committee members all reached some kind of an accommodation to the request and the charge they were given –they may have ended up updating very old regulations to make them better because the Committee does not really have the opportunity to totally reinvent this wheel. The Committee brought our expertise/knowledge/experience in dealing with the needy, running programs, dealing with government, to bear on this process. She felt the Committee accommodated themselves in various ways to moving the system forward in a way that they felt would be more effective in meeting the needs of the population.

Dr. Rarig went on to respond to some of the specific issues raised by Dr. Scanlon. She felt it would be important to separate the HPSA and the MUP/MUA designations and talk about them separately. As one point, on the geographic HPSA issues, she had responded to some of his comments about the additional geographic HPSAs designated on the basis of more refined information about provider availability because the provider availability that JSI has had access to isn't precise. The places where that information is likely to have an effect are mostly very rural, frontier, small, poor, etc that are currently not showing up. They are currently served mostly by FQHCs. They are not going to have much impact at all on the total number of people covered or the Medicare dollars. The Medicare dollars associated with geographic HPSAs are about $250 million now.

The Committee just learned that a new primary care incentive program through Medicare authorized by ACA is going to be providing an incentive to all PCPs who bill individually for Medicare patients and this has the potential for much greater consequences of at least $1 billion for PC incentive payment – explained as likely to be at least four times the HPSA bonus payment amount which we were told is about $250 million. The Medicare Bonus payment for Geographic HPSAs have been pretty steady and is not really a huge portion of the Medicare budget, so maybe it should not be such a big concern in their deliberations

Her second point was with regard to the information Dr. Scanlon provided the Committee related to the lack of effective targeting of NHSC resources, based on the analysis of current HPSA scores and placements, which they had not discussed because that was not part of their charge. Dr. Rarig felt his evidence base was not sound with his implication that money would not flow to where need is greatest. If the data were corrected she thinks it would be evident that the resources are going where the need is high. Speaking for her work in Alaska she knows that that is the case there. As further evidence, NPs are often the ones in the most rural and frontier areas with doctors serving as their advisors. Also there is a factor that some of the very highest scoring areas don't have any place for a provider to practice - certainly not physicians. Alaska requires borderline crisis situations to warrant HPSA designations. The HPSA designations for federal assistance for loan repayments make a very big difference in these shortage areas.

Dr. Rarig spoke to Dr. Scanlon's claim that the Committee's decisions will increase the discrepancy between the haves and have nots, which she did not feel was true. While the Committee would likely agree that the MUP process is not yet fully thought through, in the framework of this process there was not time allotted to create a whole new approach. The original approach actually worked reasonably well, but where it does not work as well the Committee has improved it. The Committee could ask that there be additional research and reconsideration of the approach in the future.

Regarding Dr. Scanlon's points that current allocations are not effective, she noted no evidence of widespread concern about this issue Dr. Rarig pointed out that there are populations and groups that feel underrepresented in this process, and she feels the Committee has done quite well integrating those concerns and issues.

She hoped that the Committee would have a full discussion on the MUP today to avoid designating the entire country, and that the Committee is helping HRSA to direct the funds without requiring them to deal with an absurd number of applications. She felt the Committee can do good service to the public if they can do good work to be more discriminating, which she thought everyone is happy to do.

Ms. Kuenning agreed with Dr. Rarig and presented her responses to Dr. Scanlon's comments. She expressed that she was not the same mind as Dr. Scanlon and outlined four points:

1. She did not agree that these were arbitrary decisions. The Committee reviewed reams of data, and the decisions are evidence based and empirical. Members have been brought to the table as experts, and while at times they have had to alter or make slight corrections to data where we think it's more appropriate, she would disagree with his general sense.
2. She disagrees with his feeling on the principle of the charge. She feels the Committee is here to define need and create an umbrella of opportunity. The Committee has not disregarded the impact on federal resources. She had the opportunity to check in with the author of the legislation and it is clear that the Committee's charge is to define need, not resource allocation.
3. She feels that HRSA has a comprehensive and high bar for need as to where funds would be awarded. The Affordable Care Act resources from fiscal year 2011 have been 100% allocated to homeless, seasonal, migrant workers. These are the highest need people across the country, and they were specifically targeted as having limited resources. There were criteria in the application that enabled the areas of highest need to get points to be more competitive with regard to the award. She reminded Dr. Scanlon and the Committee that the new Census data shows that 33% of the population is "low income."
4. She disputed Dr. Scanlon's claim and said there was no evidence of an increase in disparities of haves and have nots. She did not feel that getting designated does requires increases the use of consultants. Dr. Rarig through her PCO work brings a workable model in the community as great testimony since she works on the data. Where you need resources is in the application itself, and that's not something that can be changed here.

Dr. Clanon? Clanon spoke up and said that thought consensus did matter and that she compromised on some things as we struggled to reach consensus. Dr. Scanlon's dissent matters because of timing but

also to preserve provisions of what is in there. She felt it was disconcerting that he and Dr. Goodman suggested that consensus might not be that important. She wondered how they could struggle through a deadlock. She was interested to see whether or not there are places the Committee could make some changes to the point where Dr. Scanlon would feel he could achieve vote for consensus, or whether he would feel okay voting for consensus with a minority report. She wanted to know what the options were to fight through to finish work together in the way planned. She asked the mediators for guidance, recognizing that this was the Committee's "most perilous moment."

Dr. Scanlon responded that he was concerned about what would result from achieving consensus. The Committee would in effect tie the hands of HRSA from doing more impact analysis. This is important because the work may not be done. He agrees that 14 months was not enough, but at the same time the rule will be established for who knows how long; as a result, he feels it is important to vote no because he wants HRSA to have the option to continue analysis. That stance assumes he trusts HRSA. Given that they have to publish the proposed rule, they have to be able to justify it, and if they can't justify what they are doing then they should be attacked and forced to back down. He said that if he were any of the other Committee members he would not agree to what he finds uncomfortable without additional analysis. They are in the dark without knowing where they are, and Dr. Scanlon felt that it is irresponsible for him to "a pig in a poke" without knowing what it is. He's not comfortable since he does not understand enough of the impact. He agrees with Mr. Salsberg the perfect should not be the enemy of the good, but there are degrees of imperfection to consider.

Ms. Sylvester said she would welcome a conversation discussing potential solutions.

Mr. Scanlon asked if the Committee would agree to a proposal to have HRSA continue their work and modify it based on further analysis. The Medicare Commission he previously worked for would make recommendations, but Congress wasn't bound to implement them; HRSA can use the Committee majority as a well as further information and evidence to move forward. Mr. LeClair noted that consensus meant the rule must follow the recommendations.

Dr. Vaz asked if HRSA would have the opportunity to modify, and presumes they would not stop doing analysis. Mr. Salsberg responded that if there is no consensus the Secretary will take areas of consensus into consideration for drafting the final rule. If there is consensus on the rule, the Secretary is bound to accept the Committee's recommendations.

Mr. Brooks explained that his understanding of the purpose of the past 14 months was to write rules for underserved areas and populations. The allocation of resources is a separate, and frankly, political function that has nothing to do with the charge of this Committee. The Committee ends on October the 31st of this year and after that point, the members have no more input into the process. If it was the Committee's intention to let HRSA write these rules, they could have done that from the beginning. But, instead, they accepted the charge, to sit here and come to consensus. As a Committee he feels they deserve a clear cut answer, and asked Dr Scanlon if he felt they could reach consensus? Dr. Scanlon did not believe the Committee could get there and that there is a fundamental divide on where we are; he felt that the differences in the whole package are so pervasive that he felt other members might have

the same concern. Mr. Sylvester asked whether or not the Committee needed to start talking about their options.

Mr. Camacho spoke and surmised that the confounding issue for Dr. Scanlon is the data, and as he understood it is that Dr. Scanlon thinks HRSA is going to do something or can do something more with data analysis that hasn't been done up until this point. He thinks his other concerns can be easily addressed but wants to understand what Dr. Scanlon has in mind for HRSA to do in terms of data analysis that hasn't already been done.

Dr. Scanlon responded that his concerns go to more than data analysis. The data analysis shows that the Committee needs to be concerned about the number of underserved areas with regard to resource allocation since it is political, and that very often means that resources go to the areas of greatest volume and not the greatest need. There's a combination of what HRSA will do – continue the analysis to understand the impact, which may modify the decisions. In addition to doing more analysis, HRSA would be sensitive to the total number and areas of people that would be designated.

Mr. Camacho responded that they can work with the formulas to determine the number of people designated, but it is not clear what would happen with continuing analysis that would leave HRSA to modify the recommendations. He wondered what he expected HRSA would do that would lead them to modifications? He asked to hear the specifics to understand how large the problem is.

Dr. Scanlon responded that for geographic HPSAs, the Committee had heard multiple times that there is a concern of not increasing Medicare spending and those are the parameters within which they need to live, and HRSA needs to live. As HRSA further explores this, they may need to change the threshold. Dr. Scanlon asked how comfortable Mr. Camacho would feel if the upper threshold was 3500 and the lower was 2000. For MUAs, he felt that designating 33% of the nation as underserved on the basis of the Committee's skimpy information is totally inappropriate.

Mr. Camacho remembered that during the debate of the 25% versus 33% threshold, Dr. Scanlon objected to picking a number out of the air, but if he was to pick one it would be 25%. For the sake of argument, he asked Dr. Scanlon if the Committee went down to that, which also addresses the number being designated, whether it would help him to get to MUA consensus. Dr. Scanlon responded that it would be helpful but not sufficient as he is unclear whether or not the 25% threshold has any basis in fact. He said that the other issue for him was the newly developed index for the MUA. He agreed that with time it could be improved upon but that that time should be now. He did not want to take 10 more years to improve and that with additional analysis and additional thinking an alternative could be proposed relatively soon. In his experience in payment policy this happens frequently and with a lot analytical rigor.

Mr. Camacho thought this was doing a disservice to HRSA as they end up at square one. He felt that if the Committee could go through each one of the designation criteria to adjust it as much as possible and then lay out as much of the things as necessary continued analysis and recommended modifications, maybe the Committee could still reach consensus on the overall report.

Ms. Sylvester felt that there was not enough time in the following two days to debate Mr. Scanlon's opinion. She called for a break and upon return to talk about our options to move forward. Mr. Brooks objected to the break as he felt the critical issue is whether or not the Committee can get past this point. To him, options that do not include getting over the hump to consensus are irrelevant.

Mr. Hawkins reminded Dr. Scanlon that this group has been brought together for a reason, that they were all experts of some kind, and they that it would be wrong just they to leave default to HRSA because they couldn't get the job done leave it to HRSA. He reminded members that, as many have noted, the physician workforce data from AMA is widely seen as not accurate, yet it has been used as the principal data source for all HPSA – and many MUA/P – designations for the past 30-plus years. The Committee has worked hard for 14 months to get this far, and while 30 years ago people were probably saying it wasn't perfect, today they have to decide if this is better than what already exists. Dr. Scanlon has an objection, so let's see if the Committee can move forward from that.

A 10 minute break was taken at 11:13 AM.

Mr. LeClair asked what the strategy should be moving forward. The possible options for proceeding were discussed:

- Dr. Clanon proposed redefining consensus.
- Mr. Salsberg suggested a brief poll of the room with 30 seconds allowed to each person. Mr. LeClair rephrased as "with Bill or against Bill."
- Dr. Kornblau recommended determining which members think consensus will be reached versus not;
- Mr. Brooks recommended determining whether or not the consensus from the last meeting will be returned.

- Review by section and vote
- Submission of a minority report by Bill and/or others
    - Opponents resign from the committee

Mr. Morgan expressed conflicting feelings; he agrees with Dr. Scanlon that the P2P data and our impact analysis may not be correct. He did feel that at the state level the analysis will pick up a lot of areas not included currently. This is the first time he has ever moved forward on something that he thinks is a good idea but does not actually know what will happen.

Mr. LeClair asked whether Mr. Morgan thought the methodology was better than what is out there. Mr. Morgan thinks it is, but isn't sure, which is the point: if the Committee is asked what the data show, members would have to say they weren't sure what it showed. Mr. LeClair suggested that you may have to take the data you have and make a decision and move forward from that; that looking for perfect data may result in a four year Committee.

Mr. Hawkins urged the Committee not to make the perfect the enemy of the good. Neither the original rule nor the last two tries at revising this rule had more data or more or better analysis than were considered in this round. It's not perfect. The report can reflect that in strong terms and to urge HRSA

to continue to pursue perfect data. But, Mr. Hawkins feels, to say that the Committee can't or shouldn't replace an already imperfect rule with an admittedly imperfect but better rule is silly.

Mr. Holloway said that the only hope the Committee has is to stay in this room for the next two days to work this out. Change in and of itself has value in this situation. He agrees substantially with Dr. Scanlon that the intellectual underpinning of the decisions is weak, but also thinks change is important. To him, leaving status quo is the worst possible outcome. If change is allowed this time, it can facilitate change in the future. Mr. Holloway did express concern about a single consensus vote when there are five different rules. If process permits, he wanted to consider each of those five designations separately as the Committee may discover that there's greater consensus on some decisions than others which could help forward progress over the next two days.

Dr. Kornblau reminded the Committee that a NRMC was required was because the process has gone on too many times without success. This is what Congress wanted and what they intended. When this rule was passed in 1976, there were 200 million people in this country and there are 300 million now. While the numbers are going up, the resources are not; the job of the Committee is to come up with the best rule possible using the expertise and the data they have.

Dr. McBride expressed sympathy for Dr. Scanlon's point of view especially with regard to data and methods. He did not sign off on consensus at the last meeting. Each Committee member has expressed discomfort at various points. Weighting systems have always troubled him. He agrees with Dr. Scanlon's concern regarding expanding the population; the people who get expanded into the definition may be more able to compete for the funds if they have more resources, which he finds incontrovertible. Mr. Hawkins asked if he had the data to back that assertion up.

Mr. LeClair clarified that the consensus votes were based on various pieces rather than the whole, for which Dr. McBride expressed support.

Dr. Rarig agreed with Mr. Holloway, that the proposals so far are going in the right direction of improving on the old rule. She recommended focusing on the instructions for HRSA or for revisiting, especially for those certain things that need to be addressed in five or ten years.

Ms. Hirota thought it was helpful to hear Dr. Scanlon speak but had problems with his premise that the Committee is better off just being advisory than rule-making because that fundamentally questions the ground rules agreed to in the beginning:: to reach agreement in all aspects of negotiation. She asked a procedural question, does the Committee not have to agree to the ground rules, to negotiate in good faith? She wanted to determine whether the ground rules are moot and, if they are, to decide as a group that however many can move forward. Holding the whole process hostage seems stupid, and Dr. Scanlon can step away from the Committee if he feels these ground rules are not something he can commit to. He can do a minority report, or the Committee can agree in part. But, if the Committee agrees in part, all have to agree to negotiate rather than hold the process hostage. If Dr. Scanlon doesn't have to adhere to the ground rules, Ms. Hirota asked what good the ground rules are for.

Dr. Scanlon replied that he did not interpret "negotiate in good faith" to mean a blank check. He has been negotiating in good faith, being clear from the beginning where he stood and understanding when he wrote his email that the Committee was in a different place. Consensus was never achieved at the past meetings, just agreement on elements – the elements together as an entire package means he cannot vote yes. While he understands the need for change, he also recognizes the inertia in Washington. HRSA will not re-review in five years, it's not reasonable.

Ms. Hirota appreciated the clarification and accepted that if Dr. Scanlon was willing to move forward and evaluate, then the Committee can move forward; otherwise, they need to recognize that they will need to convert into an Advisory Committee. Dr. Scanlon replied that the package as a whole does not pass the laugh test and since new information isn't going to come in the next 36 hours so, he felt a vote may be made without fully understanding the implications and that there would be no clear reason to change positions.

Mr. Owens felt that there should not be surprise that the information may not be perfect, which is why PCOs have worked extensively with the data and the process to receive designations. He never understood that to be up for change. As a PCO, his job is to be involved in the HPSA process. A few months later many of the Committee may stop having a conversation about this, but PCOs will continuously have discussions around it and will also understand our decisions. He felt the Committee needed to move on and start reviewing the document. He thinks that the Committee is in a time of change and as a result they have to rely on the best information they have.

Dr. Vaz expressed concern that the Committee was wasting time when they could be reviewing the documents to see where consensus exists; no one including Bill ever promised to give up everything to reach consensus. He commented that if consensus is not reached then, that that is okay.

Dr. McBride agreed with Dr. Vaz and referenced Dr. Taylor's email suggestion of going through the report, document the votes, and highlight different areas of disagreement.

Mr. Camacho requested that the Committee be specific and take responsibility for progress. The Committee needs to determine what will be done next, whether it's a majority/minority report or some other option. Based on the conversations he has heard, this process will get locked up because after so many months they are asking the agency to do our work. To the extent, either section by section or by formulating the majority report, that the Committee can be specific, which would help determine how to meet consensus and how to vote on the report and not give a blank check to HRSA.

Mr. LeClair suggested that if the Committee goes item by item individual members have to say where they can't live with the proposal and what specific changes they would suggest to make it acceptable.

Dr. McDavid explained that her concern is what happens to the ones we don't agree on and Mr. LeClair suggested the group would have to decide whether or not to move forward with a minority report. Ms. Sylvester suggested that the Committee assumes that with a no vote that the Reg Neg process, HRSA will issue a proposed regulation. There is a proposal for HRSA to establish an Advisory Committee that will then begin to look at some of the data issues/concerns and to look to see if there are modifications

or changes to the interim regulation that will have been issued. The option would conclude this process with the agreement to go forward with the establishment of an Advisory Committee to look at future issues.

Ms. Ms. Kuenning recommended that the Committee move forward with review of each element and hold bigger votes until after. The Committee gave thumbs up vote with 2 2abstentions.

Dr. Clanon felt that if the Committee cannot reach consensus that #3 to vote on each element separately, is the best option, but the Committee needs to be aware that that leaves everything in the hands of the Secretary. Mr. Salsberg re-read the Federal Register notice and noted that consensus on individual items would thus be valuable.

Ms. Hirota expressed support to review piece by piece but wanted to clarify that the process needed to be managed and that the items that were not voted yes upon could not be left hanging and the Committee needs to get to the vote on the whole..

Dr. Larson reminded the members that the legislation says this is an interim final, and not a draft, which means that the 892 comments that happened last time, don't make a difference, frankly, because it goes into effect. Those comments may do something politically but it's a different ballgame. If we don't reach total consensus – since the regs don't say partial consensus on pieces – that does not obligate any of the organizations at the table to support it. It does lose HRSA the ability to have those organizations go forward to their constituents to explain and promote the new rule, which is a huge loss. If the Committee does not reach consensus, it's all thrown to HRSA. Substantially the rule may look the same but some key issues may change. She recognized that this may be the best the Committee would do but would hate for the downgrade to Advisory Committee. She recognized the sacrifice of all the members to participate including her own sacrifice in terms of income, etc.

Dr. Kornblau clarified with Dr. Scanlon if there was a possibility of voting for the whole if we go piece by piece-some maybe we can agree on, some may lack good data and analysis. He responded that there are some things with small pieces, and it's not necessarily a reflection of the data, but the way the Committee used some of the data. Dr. Kornblau explained that she was trying to distinguish whether Dr. Scanlon can agree at all in the big picture because he's not having a problem with the individual elements – aside from a few. He said when the package is put together is the problem.

Dr. Scanlon reminded the Committee that rarely have they had a 100% of people agree to anything; the no votes were queried to as whether or not members would fall on his or her sword. Putting together the scattered negatives is what leads him to vote no on the package; based on the cumulative sum of no votes. In considering 70% confidence, the question is how many no votes does the Committee have before it votes no.

Mr. Hawkins said he would follow along but thought someone had raised a valid concern, which is that if we do agree to go through and look at the elements and perhaps break out our work into five or six pieces there's still a possibility that that will be seen as a full consensus and therefore have the weight it would in the same way as it would if we reach consensus on everything. He would be willing to do that

if there's just no way full consensus can be reached. He would like the Committee to consider the development of a minority report before they vote on the elements. While he respects and admires his stand on principle, Dr. Scanlon's refusal to agree to consensus because that would imply that he agrees with the full rest of the report, threatens to thwart the beliefs, desires, and work of everybody on the Committee, including him – and their efforts over the past 14 months. Mr. Hawkins asked Dr. Scanlon if he would be willing to accept filing a minority report as part of – embraced by all of us – as part of the consensus – giving him the right to have a separate authorship weighing out the issues that he raises. Dr. Scanlon reminded Mr. Hawkins of the legal implication of publishing a rule. So, with consensus and a minority report of disagreement it is unclear how that affects consensus.

Dr. Clanon suggested that the only way for the Committee to proceed would be to redefine consensus and wanted to reexamine their option for that.

Dr. Kornblau reminded the Committee that the bottom line is that if consensus is not reached then the old rule stands, and HRSA's decision may or may not be accepted.

The Committee adjourned for lunch, and upon return would go through the report chapter by chapter reviewing areas of agreement and disagreement with the goal of identifying areas of full consensus.

The meeting re-convened at 1:18PM.

COMMITTEE REVIEW OF THE REPORT

Mr. Salsberg directed the Committee to the report and its summary table and started by going through section by section. Ms. Sitko of HRSA clarified that the comments included in the summary table were only those that the Committee would need to review.

Introduction and Conceptual Framework

The introduction had no additional comments.

For the conceptual framework section, Drs. Rarig and Kornblau and Ms. Kuenning agreed to add "do no harm" to the text. Mr. Salsberg suggested adding an additional sentence regarding the simplicity, noting that this includes making it easier for communities eligible to apply. McBride spoke up that he preferred the already existing wording from the introduction. Dr. Rarig presented the process notion of of holding the items that need to be discussed further. The Committee voted to hold the "do no harm" idea.

RSA

For the RSA section, Dr. Larson asked for the second paragraph to be put on hold. Mr. Holloway will work with HRSA to clarify the wording. *P2P*

For the P2P section, Dr. Kornblau shares the concern of Ms. Kuenning that PAs and NPs practicing obstetrics should be weighted at 0.25 FTE, equivalent for OB/GYN practices. Ms. Brassard clarified that if an NP is working for an OB/GYN, he or she would not be doing surgery – but a PA would be. NPs should not be moved to 0.25 in weight. The weighting was put on hold.

Dr. Larson noted that the discussion of back outs throughout the report was inconsistent –and she felt that it should be made consistent. She also did not remember the Committee recommending survey guidance as referenced on page 19, which Ms. Sitko explained came from Workforce Subcommittee materials in June of 2011. She asked for that item to be placed on hold. Dr. Kornblau asked to remove data for specific disabilities. Ms. Hirota asked for concerns regarding linguistic populations to be placed on hold. Dr. Scanlon thought that the reference to the yo-yo effect should be placed on hold since there is no evidence of one and it reflects an area HRSA should be looking into. Mr. Salsberg explained that he continues to have concern regarding back outs and thus is not prepared to support that specific provision, but is willing to vote for the package in its entirety. Ms. Smith asked for the sentence regarding Indian Health Services and practices on page 20 to be placed on hold.

Population Counts

Dr. Scanlon asked for the section regarding institutional populations – especially for nursing homes and college dorms – to be placed on hold. Ms. Kuenning let the Committee know that more information regarding age and gender would be needed.

REVIEWING THE COMMITTEE REPORT, REDUX

Introduction and Conceptual Framework

Reviewing the conceptual framework again, Dr. Kornblau provided the compromise language "with the goal to do no harm." Dr. McBride felt that was contradictory and in fact the report acknowledges that it is difficult to achieve that bar. Ms. Kuenning let go her interest in the provision and the Committee moved forward without adding this language.

RSA

Reviewing again the RSA section:

Dr. Larson asked that the "generally" remain in, and to take that issue off hold.

In response to a written comment on the draft report, Mr. Camacho stated that the only reason "hospital service areas" would be defined is with regard to benefits and asked why it would babe included since the Committee is only dealing with primary care.

Dr. Larson felt that the thresholds have now been defined and thus now needed to be included. Ms. Larson felt that an ideal had not been set and it would help define it in order to understand the phrase: "80% of ideal provider capacity." She wanted to understand how to operationalize it. Mr. Holloway

explained that the principle was important to include – that he lives in a 5000 person community without doctors if the community down the road with tons of primary care providers is not accounted for. The regulation needs to have a means of distinguishing nearby service areas that can or cannot accommodate the surrounding areas. Mr. Camacho suggested to include this in the body of the report rather than as a footnote.

Dr. Rarig felt that since NPs and PAs are being included that a 1500:1 or 2000:1 threshold would be appropriate to put in. Mr. Holloway put forth a motion to change the language to read "P2P ratio not to exceed 2000:1," but Dr. Larson put the element on hold and asked to punt to HRSA if necessary and Dr. Rarig expressed a desire for more time to think about it.

With the exception of Footnote 6, the Committee agreed to the rest of the RSA section on a vote of 22-0.

P2P

With regard to the P2P section: Dr. Rarig said that 0.75 FTE for NPs and PAs was used for the purposes of testing but for the rule she thought the Committee was recommending that actual surveys be conducted to determine the allocation when an actual designation is submitted. She wanted to distinguish for designation the 0.25 if their credentials are surgery and 0.75 if they are doing primary care. Ms. Brassard agreed and pointed out primary care is being done in OB/GYN offices. Ms. Kuenning pointed out that certified nurse midwives (CNMs) are included at 0.75 even though they may be doing surgery. Ms. Nickerson pointed out that they could be at the hospital delivering babies and not necessarily 75% time primary care, but Ms. Brassard explained that the data came from a CNM organization that they work 75% time primary care in the clinic. The Committee gave a thumbs agreement to keep the CNMs at 0.7575.

Dr. Larson felt that state loan repayments should not be backed out; Mr. Holloway explained that the Workforce Committee decided in favor of the back out because of its reflection on the National Health Service Corps.

Dr. Larson also felt that the section on surveys should be removed as HRSA would have to take on that responsibility which would be huge. Ms. Kuenning said that she and Mr. Holloway had been working on that and there was variability between what the PCOs ask. She felt that the Colorado survey was a good prototype and wondered if the Committee could agree to use it as a prototype for the essential elements of a question in a survey. Dr. Larson felt that a survey would cover some but not all of the population and doesn't know how the Colorado survey relates to what is in the document, nor did she think the Committee had the ability or time to delve into those questions right then. Mr. Salsberg and Dr. Kornblau recommended an example survey and who would be surveyed. Mr. Hawkins recommended keeping the first two sentences but dropping the rest of the language. Dr. Kornblau did not think surveying individual providers was the right way to get information and instead would be happy with the phrasing "survey individual provider practices and other groups providing services."

Dr. Rarig pointed out that HRSA may have to decide on using alternative data sources, and in the past they have allowed applicants to use Medicaid data to validate. Mr. Turer of JSI explained that to be able to do a P2P ratio of the population that there needs to be a way to quantify the population and the providers.

Mr. Scanlon expressed an inability to agree with the yo-yo effect because he has not seen the data to know if there is in fact a yo-yo effect and to what extent it exists or what its impact is. He felt that that statement needs to be information driven and not based on Committee feel. Mr. Camacho asked why the Committee couldn't say "the committee was concerned about a yo-yo effect but not having sufficient information asked HRSA to study." Dr. Scanlon agreed with that, but it was not agreeable to the rest of the Committee. Ms. Nickerson said that if that statement was not included that she might have to fall on her sword as it would for sure affect rural health clinics and Mr. Morgan agreed. Dr. McBride expressed sympathy for Dr. Scanlon's position and asked whether or not language was needed regarding the Committee recommending "further research" for items that aren't entirely fleshed out.

Dr. Kornblau pointed out that data isn't just numbers and that people like Ms. Nickerson, Mr. Morgan, and Ms. Smith represent people on the ground as experts who see the effect. Mr. Salsberg felt the issue is not that there won't be a yo-yo effect but that the current proposal significantly expands back outs. With the new proposal, about 5% of nation's practitioners will be backed out. As currently written the Committee is saying it may not be appropriate for widespread use. Mr. Hawkins explained that he cannot agree to drop the entire section on back outs. If the Committee wants an impact section, it should be easy to are run the data without the back outs to understand the impact on FQHCs and RHCs, as well as NHSC and IHS sites. He noted that not counting 5% of all providers mean 95% are still being counted which still sounds good to him.

Mr. Camacho suggested language that noted that this was a departure from current practice recommending the expanded back out but there were concerns; however, an overwhelming majority of the Committee refused to exclude the section about the yo-yo effect. Dr. McBride suggested language that would indicate an unfinished Committee recommendation for further research. Dr. Scanlon noted that it would tie HRSA's hands to use the expanded back out even with further study, and he would prefer no recommendation but to study the issue further.

Mr. Morgan explained that in the 2008 NPRM HRSA had backed out them the CHCs' providers, so there must have been a reason to do it then, and in this case we're just asking they do it again but including RHC providers. Ms. Jordan of HRSA explained that while that was correct it was a multi-tiered process at the time, from no back out to partial to full back out... Mr. Morgan responded that he was trying to demonstrate that the idea for this didn't come from outer space and that it would be appropriate for HRSA to do additional research and update the methodology if they have data to show that it's a bad decision.

Ms. Kuenning offered that when the Workforce Committee was working on this she thought it would be agreeable to HRSA since they were backed out in NPRM 2. She agreed that 5% of total physicians are a small amount. The term "yo-yo effect" came from HRSA. Ms. Jordan explained that this was a different

model. Mr. Turer explained that in the models JSI was running, they had been backing out what they could based on the data they had available, which for FQHCs was approximately only 50% of the actual providers, and for other groups the margin of error was undetermined. Dr. Vaz supports Mr. Hawkins's recommendations to keep in the provision and direct HRSA to do further research. He expressed concern about giving HRSA an open door without being sure what the process would be moving forward. Mr. Salsberg notes the difference between the NPRM2 model (tiered) versus the current proposal and suggested a way to address it differently-by program linkages. For example, NHSC, J1, and RHC providers would be excluded from the HPSA formula, since those placements are tied directly to the designation, and for MUAS the CHC, LAL, J1, and RHC providers would be excluded since they are tied to the MUA designation.

Dr. Rarig expressed agitation in thinking the yo-yo effect had been decided months ago, and was upset that HRSA didn't come forward with more information on field strength vs. existing designations. The rural contingent could have brought more information if they had known it was necessary. She stated that she could show areas where the yo-yo effect is a problem.

Ms. Kuenning and Mr. Morgan remember two votes for consensus on this issue; both Dr. Scanlon and Mr. Salsberg did not vote for the back out earlier and they expressed their concerns at the time. Dr. Scanlon thinks that knowing the impact nationally rather than at a state level is an appropriate thing to do. He expressed annoyance that so much time has been invested in this without a sufficient analysis of what issues are on the table.

The Committee called for a break. The session began again at 3:23PM.

Dr. McBride read proposed language to encourage further research. Mr. Camacho wanted to add Dr. Scanlon's points to that language. Mr. Holloway clarifies that the service areas that have lots and lots of providers will have a small proportion of the safety net providers, but, in areas where there are very, very few providers, many or most of whom are safety net, it's almost undeniable that there will be an effect. The only area where this might come into play – and where the debate really is – is rural communities. The Committee's rural experts seem to feel strongly that this effect would be real in those communities so that should be the core of this discussion. This is a fairly narrow set of designations as a proportion of the whole.

Dr. Scanlon explains that he is uncomfortable with the directive to HRSA to do something now and then to study the impact later. He recommends that "the Committee has a concern about a yo-yo effect and believe that HRSA needs to examine the importance and the appropriateness of excluding some or all of these providers for the calculations." He was worried that as the ""yet defined RSAs" are defined, what the impact will babe on the number of people who wind up excluded.

Dr. Clanon notes that the Committee is running behind schedule and recommends either a vote or to move on.

Mr. Hawkins offered as a concession a concession option as a possible compromise to reach consensus. What if non-NHSC providers working at FQHC/FQHC look-alikes and rural health clinics were not backed

out for HPSA purposes but were backed out for MUA and MUP, similar to Mr. Salsberg's earlier suggestion. A concern about how to handle RHC providers was raised and he withdrew them from his proposed "not backed out" option. Mr. Hawkins is willing to give on that if Dr. Scanlon shows no objection to the 1500:1/3000:1 thresholds. Dr. Scanlon explains that his problem is that there are certain areas where he is uncertain as to the impact of some of the decisions that have been proposed and he'd like to know those impacts first. He does not understand the thresholds when he looks over the impact data. He does not understand the differences between currently and newly designated HPSAs how in terms of the calculations – the number of people increased by a great deal without increasing spending and by dramatically changing the ratio. His problem is not with the thresholds, but with the data. Mr. Salsberg thought Mr. Hawkins's proposal is a good direction to move in, but Mr. Hawkins said that, with Dr. Scanlon's refusal to agree to his proposal, he was withdrawing it as an option. Dr. Rarig contributes that in the Workforce Committee reports, the offset came from the change in the P2P and the counting of NPs and PAs, and the back out of PA/NP/MDs if they're in these federally supported programs. It was her understanding that much of the Committee conceptually understood that these resources were federal, and currently it is the process that non-NHSC and so on are not backed out from HPSA and MUA applications – so, they're counted. She felt that HRSA should study it further but asked for a vote

The Committee called a vote on the original language, with 16 for and 4 against, and 1 abstention.

Mr. LeClair brings up the P2P issue of counting residents of nursing homes and college dorms. Mr. Brooks and Ms. Brassard felt it appropriate to strike both from the list of exclusions and would add them to the population count. Ms. Jordan explained the categories come from the Census regarding "resident civilians." The Census data has a specific approach to counting institutionalized populations including nursing homes and dorms. Mr. LeClair calls the question, and all members vote yes.

Mr. Salsberg called a vote on the P2P section as amended, for which there are 3 no and 18 yes.

MUA

The Committee begins discussion on the MUA section. Dr. Larson felt a number of things were missing from the discussion, including descriptions and tables that need to be added. She clarified that if the Committee is fully in agreement in the understanding of the process as explained, then her comments are just directive to HRSA to include clear language and include the tables in the appendix.

Mr. Turer said that a table from the last meeting showed the 100 point high and low thresholds for each of the parameters with a bit of information with on how they were developed, For someone to actually implement this model they would require those tables. Mr. Salsberg suggested that the more detailed methodology could be included in the appendix. Dr. Larson believes that there needs to be a point table for easy replication, which Mr. Turer agreed with.

Dr. Larson suggested using a different term than IMU, which Committee members agreed with.

Dr. Larson recommended different phrasing from non-white to avoid confusion and provide clarification for the racial group barrier. Mr. Turer explained the score will always be equal or higher for non-white than it would be for any specific racial group. Dr. Larson asked if recommended data sources should be included, and Mr. Salsberg thought that it may not necessarily be put into the regulation but instead in the report.

Mr. Salsberg reviewed the final decisions for MUA, including the 33% threshold and 200% federal poverty level for about 102 million Americans designated. It's a very fundamental methodology for HRSA and for the resources. He asked if there were questions or concerns with MUA methodology. He personally was prepared to accept the recommendations of the Committee.

Dr. Scanlon reiterated his concerns from the morning with the MUA proposal: the conceptual framework of using an index rather than a ratio, the variables themselves and whether they're sufficiently discriminatory amongst how bad the need is, and not having a sense of the meaning for designating 33% of the population. He recommended opening up some of these issues for HRSA to research.

Mr. Salsberg recommended discussing guidance to HRSA in the report. He recognized the importance for HRSA to target resources. He expressed less concern with the total number designated as compared to Mr. Scanlon as there are a lot of areas of the country with high need, but does find it important to urge programs to effectively target. He supports additional language urging programs using MUAs and HPSAs to develop methodologies to identify areas within the eligible populations to ensure that resources are going to the highest need communities.

Dr. McBride expressed agreement with Dr. Scanlon and recommended to vote. Sees a minority report in the future as it would be more effective to express his concerns there.

Mr. Salsberg calls the vote for the current draft of the MUA without additional language. 16 vote yes, 2 vote no, and 2 abstain.

MUP

The Committee reviewed the MUP section. Mr. Salsberg expressed concern that the testing of the model developed showed it could potentially designate 93% of the country for low income, which seriously inhibits the ability to target. Mr. Turer presented why this is happening and what can be done. Mr. Turer presented a pre-impact test, which assesses only a few parameters that come out of the decisions made at the last meeting. As a result of those decisions 90%+ of population could probably be designated based on low income. The real impact test of low income involves calculating the P2P specific to the low income population and who is available to see them and potentially looking at the impact of health status of the population. . These results reflect scoring only the population-specific scoring of barriers and ATP.

Mr. Turer presented to the Committee a slideshow that demonstrated this process. (Attachment)

Mr. Turer pointed out that the question is how you estimate what the barriers and ATP factors would be to be scored for the low income group. From the American Community Survey (ACS) and the long-form Census poverty, but not low income, is reported by race. So the % non-white is not for low-income; for the poor or Hispanic, they estimate that that will be a lot closer. The % uninsured being used is the same thing as for the % overall. ACS reports % uninsurance by income category. We're looking at under 200% of poverty using a relative factor within a given state. As discussed last time ability to pay which is % low income for every area now scores 100, so as they're all low income they'll all be at the top of the scale. P2P – which is the thing that is used to most discriminate – is the same, for the community as the whole. It assumes the poor in the community have at least the same access as the community as a whole, so is not doing the core of what the pop designation is designed to do. Same thing with health status: it's the same score for the subpopulation as it is for the whole community. Other barriers are held constant to the geographic designation, so only those barriers for which a proxy could be obtained were changed. Scales and thresholds remain unchanged. That was applied to the low income population which is the same as what's done in the current rule – the scoring and the thresholds are not different for a MUP vs. a MUA. The difference is the current rules do not let an applicant come in at 100% for a low income designation. So barriers and ATP are not direct measures of underservice, but instead groups at risk for underservice. The current weighting of these two factors is 60 with 40 points for barriers and 20 for ability to pay and low income; the threshold cutoff if 54.3, so these two factors alone can exceed the cutoff with no other factors considered. The preponderance of weight in the MUP is based on risk and not on P2P or population's health status, which gives a hint as to why so many places get designated. Same thing is true for the mid-range of the population HPSA. The highest threshold is 80, and 50 of 80 points would babe awarded automatically. One would expect a worse P2P in those areas. The test assumption used is that low income has the same exact P2P as the overall community they're in. If you look at the top two, they're the difference in race and percent Hispanic. When you get up to 100 you're awarding for race for example more than twice as many areas get 100. Low income highly associated with race, Hispanic too to a lesser degree. By focusing on the low income designation the focus is specifically on the result of that barrier being measured. A low income group that's going to have a challenge paying for health care is displayed here as operationalized in the community (providers who won't see Medicaid, etc), with the outcome as low income. Scoring shifted well into the 70s if not 80. Mr. Turer posited that if the model was run with locally defined service areas that almost 100% of areas would be designated. 87% of the areas that don't qualify as an MUA come in as an MUP. It's up for debate how much of an issue this is or what to do, but that's reasonably factual as to how that would score out.

For a population HPSA, the change in methodology has resulted in designating about 70% in the mid-range. How many are in the mid-range would probably increase in a real population designation using local RSAs and P2P data.

Mr. Turer told the group that the question is how to fix this. The scale doesn't need to be expanded or shifted to fit the values, but the scores do fall higher on the scale. Depending on which population group is trying to be designated, the scoring will change. An LEP would score higher than low income. A focus on the uninsured would skew the factor 100% towards that group. With the menu approach, shifting

one factor higher results in being high on a number of factors. New weighting could help, but he thinks there's an underlying scoring issue with applying the barrier and ATP rates to a population specifically chosen for those reasons. Adjusting the threshold would lead to a different threshold for every population. The current methods score risk at the community level only for a MUP.

Dr. Larson thinks it should be obvious that JSI came up with so many low income people since it scored areas where there may be five people, and if the Committee refers back to the population specific RSA discussion in the report it would probably not allow for those five people to be considered for designation as a low income MUP. Mr. Turer agreed that this was possible but noted that this did raise the questions of a minimum population.

Mr. Salsberg asked the Committee what the options were. One strategy is to require low income as 30% in an RSA in order to be designated, but he didn't think that made a lot of sense because that might change for larger communities. He thought there might be an option to set a limit. Dr. Rarig felt the data run showed that the group needed to review minimum populations. Mr. Turer pointed out that minimums would not change the fundamental scoring issue; once the minimum is satisfied, regular scoring kicks back in, although he did not think a minimum would exclude many areas.

Dr. Rarig noted that this did suggest reviewing the need for a minimum; and that this result came from the consequence of the decisions made in consideration of resources and the need to find means to discriminate. The laundry list of variables was narrowed down, and these results are a consequence to the heavy focus on income and uninsurance in the model. The Committee is constrained by operating in a system where the MUP does not relate directly to area promise to serve that population as part of a grant funding process. She asked the Committee to consider their wiggle room.

Mr. Turer said that when reviewing the logic of the population designation for MUP, the reason for not doing population specific scoring on the demographic factors is probably a practical one with regard to data availability. Looking at the community and examining a specific population within it would likely cause the least disruption and stick closest to the history. P2P was always calculated for sub populations but the other two were not. From there, using a walk back would leave the demographic risk factors at the community level, so the only variant between an MUA and an MUP is when a substantial difference in P2P or health status is seen for an MUP. The one thing to be careful about is that P2P is the most measurable part of an MUP and it's currently weighted at 20%, which is where the primary differentiation between an MUA and an MUP lies.

On the HPSA side the opening statement might be to keep health status to the extent it can be discerned, because again there's a supposition that low income shouldn't be sicker or have less access than everyone else, not that the low income would have the same demographic. Mr. Turer proposed maybe removing the low income from the middle of the graph and leaves it based solely on health, which is what Mr. Holloway suggested and doesn't automatically move the threshold down to 1500:1.

Mr. Salsberg recognized this as a particularly difficult issue especially since it was only discovered in the past week. He asked Committee members which areas would be useful to explore further.

Dr. Clanon caucused the Committee to consider the options overnight and discuss in the morning. Most Committee members favored this option, so. So further discussion on MUP was put off until later.

Geographic HPSAs

Mr. Camacho asked Mr. Turer if the MUP analysis worked also for the population HPSAs; Mr. Turer explained that the midrange of the impact for HPSAs was narrower, but the scoring was still affected.

Mr. Hawkins asked what the threshold for the midrange HPSA was and what factors were needed to qualify for a lower P2P. Mr. Hawkins recommended stronger language for the MUP section – "expects" and "would" versus "anticipates" and "could" – and wanted clarification on whether or not the eligible providers were different than those eligible for a geographic HPSA. He also clarified language on page 36 to specify "unique" or "special" or "identified" rather than "general."

The Committee discussed the geographic HPSA section. Dr. Scanlon said that he still did not understand the impact analysis. TheP2P of the current HPSAs is 2145:1 and the P2P for the newly designated HPSAs is 3500:1; that is a drastic change that I do not fully understand. There is a major increase in terms of population and yet the Medicare spending goes down. Maybe that is possible because the country has more people and fewer doctors, but reviewing the currently designated, 70% of the newly designated areas are designated and the ratio there is 3486. So what is the P2P ratio of the 30% who are not designated? Mr. Turer responded that it is the number of people and not the number of providers. While there are still CMS questions the P2P is higher and results in lower Medicare dollars. Those eligible for Medicare money are only being counted where the providers are actually located, so the dollars would be lower in those communities – consider it as Medicare money per population. Dr. Scanlon reiterated checking the data, particularly so Medicare spending is not increased. Mr. Salsberg agreed and wanted to be sure that the methodology addressed areas with fewer practitioners. Mr. Salsberg also pointed out that the newly targeted areas were those with the higher ratios and therefore higher need.

Mr. Hawkins did some calculations using table 1.2 and found a difference of over 9000 providers in the areas that would not be designated.

Dr. Rarig expressed confusion about the distribution of Medicare money, because many of the designated areas don't receive the Medicare bonus because of the way they bill, such as FQHCs and RHCs, or they are NPS or Pas that don't qualify for the bonus. They're not managed care necessarily but they may not do billing in a way that gets the bonus.

Dr. Vaz pointed out that in the geographic HPSA tables a number of frontier areas including Alaska and Wyoming would not be designated with the current model, which might reflect that something is not working. He supported Ed and Bill's interest in looking at the data more closely. Mr. Turer pointed out that one problem with the data was that FQHCs do not always have a specific street address and thus

the geographic match method may not work in those areas for the back out process. There are plenty of specific local examples and he would not be surprised to see a similar situation specifically in frontier areas given the number of rural routes and P.O. boxes. Ms. Jordan of HRSA also reviewed the data, for Montana and for current HPSAs located in the ASAPS, and in some cases the local data were significantly lower. In a smaller place one or two providers makes a huge difference. The overall completeness of the data and inability to completely identify the back out area was a concern.

Dr. Rarig pointed out that the updated frontier methodology would not result on a "free pass" or extra designations for Alaska; rather, that those frontier areas with careful provider counts would generally remain design table. She observed that the inclusion of PA/NPs could be problematic in those areas, but noted that if CHC employees were backed out the areas should remain eligible. She stated that in Alaska specifically, some areas that had come in and out of geographic HPSA designations may not be eligible, but that it would not be as dire as Mr. Supplitt had feared.

Mr. Turer confirmed that JSI was planning to do further analysis regarding the impact.

Dr. McBride referred the committee to a comment on page 32 of the document, observing that he too had difficulty understanding the exponential curve. Dr. Scanlon suggested that the addition of a graph would be helpful. Ms. Sitko of HRSA confirmed that there would be a graph added. Dr. Larson suggested that, in addition to the graph, more colloquial language to describe the curve would be helpful.

Dr. McBride suggested that the language about frontier areas on page 33 clarify that the rationale for the updated methodology was to account for inaccuracies in the data rather than to protect existing designations. Mr. Salsberg added that additional comments regarding lower productivity in sparsely populated areas would also be helpful and noted that this would be included in the report. He then confirmed that this would also include context for why the productivity was lower.

Ms. Sitko confirmed for the committee that she would try to provide both a track changes copy of the report and a clean copy to facilitate review.

Mr. Salsberg and Ms. Sylvester queried Mr. Turer as to whether he was rerunning the data; Mr. Turer replied that this would depend on what the initial check of the data revealed.

Mr. Salsberg then asked the committee whether there were any additional concerns in the geographic or population HPSA sections aside from Dr. Scanlon's concerns regarding documentation. Dr. Rarig observed that the MUP scaling issues would impact population HPSA and stated that the group should focus their comments on geographic HPSAs alone. Mr. Salsberg concurred; stated that the group would re-review tomorrow, and opened discussion on the facilities section of the report (pages 37-41).

Facilities

Dr. Clanon provided commentary on behalf of Dr. Wilson, relaying Dr. Wilson's question regarding the reduction in the number of groups listed. Dr. Clanon stated that Dr. Wilson was remembering correctly, but that the cut occurred in a different place in the document under the Facility MUPS

Dr. Clanon then opened discussion regarding the term excessive ER use. She noted Ms. Kuenning's initial desire to use existing language but noted the shared feeling that the existing use of "excessive" didn't seem completely appropriate. Dr. Clanon stated that "ambulatory care sensitive" was the compromise reached. Ms. Jordan stated that the ACS terminology came into being after the current regulations were written and that the current practice was to use "excessive ER use for primary care conditions."

Dr. Clanon noted the continuation of the statutory automatic designations for FQHCs and RHCs. She reviewed the establishment of the magnet clinic, the safety net facility designation, and essential primary care providers. She directed the committee to the definition of insufficient capacity and called for questions or concerns. She stated that the correctional facilities language included the committee's recommendations from the previous meeting, including county correctional institutions.

Mr. Camacho asked for clarification regarding the legality of the committee's county correctional institutions recommendations and asked for insight into the consequences if the general counsel opinion {of illegality} held. Mr. Salsberg responded that the Secretary would not put into place a rule that was contrary to law and that the recommendation would be severed if found to be illegal.

Mr. Camacho asked whether any additional guidance was available and stressed that he did not want the entire rule to be challenged on the basis of an illegal provision.

Mr. Brooks responded that he was completely comfortable with general counsel taking whatever position they wish on it and stated his opinion that if general counsel took exception to this particular section of the rule, then they would knock out this particular section of the rule. He stated his opinion that the rule was modular and that an objection to this section should not impact the rest of the rule.

Mr. Camacho stressed that the report did not have a severability provision and repeated his concern that this section could leave the rule open to challenge. Mr. Brooks responded that the report did not need severability, as the Secretary herself had severability. Mr. Brooks expressed his opinion that to focus the severability issue on the question of county correctional institutions in particular was inappropriate. Mr. Camacho responded that this particular section of the report was the only one, to his knowledge, where general counsel had ruled the language illegal.

Mr. Salsberg provided additional context from general counsel and noted that general counsel continued to state that their interpretation was that the statute expressed a congressional intent to exclude county facilities. Mr. Salsberg added general counsel's opinion that the legislation had explicit references in a number of places, thus the absence of a reference to counties in this section is an indication of Congressional intent. Mr. Salsberg clarified that his comments were based on a review and discussion rather than a new written opinion and clarified that these comments were the result of a new review with OGC.

Ms. Kornblau observed that consensus seemed elusive and asked for a vote.

Dr. Clanon responded to Mr. Camacho's concerns, providing her understanding that the committee was not likely to achieve consensus on the whole rule in any event. She stated that in her opinion, it was consistent with the definition of need to include these facilities and suggested that it might be valuable to add a sentence on severability to address Mr. Camacho's concerns.

Mr. Camacho questioned whether the process of voting on the recommendations separately would cause the facilities section to be a stand-alone recommendation. Ms. Kornblau asked Mr. Camacho if this meant he would be more comfortable voting on whether to keep in the county correctional language rather than the facilities designation section as a whole. Mr. Camacho said yes.

Ms. Sylvester called for a vote on the inclusion of county correctional facilities. 15 Committee members voted yes, five no, and no abstentions.

A vote was then called on the overall facilities HPSA methodology. 18 Committee members voted yes, no members voted no and two members abstained.

Geographic HPSA

Ms. Kornblau asked Mr. Turer whether he had additional information that would assist the group in coming to a vote on the geographic HPSAs.

Mr. Turer said he was working on additional nuances to the analysis, but that the information already pulled would provide helpful context. He provided the following summary:

- Of the areas redesignated and lost there are approximately 33 million people total with 15,000 providers
- The 69% of areas redesignated represent about 21 million people and 6,000 providers, which leads to a P2P of 3500:1 roughly
- In the areas losing designation there are 12 million people – and and 9,363 providers, which leads to a ratio of 1281:1.

Mr. Turer noted that a simpler way to summarize the data was to say that the areas redesignating accounted for 64% of the population but only 40% of the providers in current HPSAs, which results in a very high P2P ratio. He continued to say that in the areas losing designation, almost reverse is true, with these areas accounting for 36% of the population and 61% of the providers in current HPSAs. He summarized to say that essentially, half of the providers but only 40% of the population were being removed and that this resulted in a dramatic shift in P2P. He stated that his staff was currently trying to pull the numbers separately for MDs and total P2P to approximate the impact of the back-outs. He noted that the report was right, but that the "why" behind the numbers was more difficult to tease out.

Dr. Scanlon noted that this explanation was helpful. He also noted that the NP/PA/CNM inclusion may be driving this a bit; Mr. Turer agreed that this was partially true.

Mr. Salsberg questioned whether the committee had any other issues to raise and proposed a vote. Ms. Sylvester called for a vote to accept the language as it appeared in the report on geographic HPSAs; prior to the official vote, the committee had additional questions and comments as follows:

- Dr. Vaz asked whether additional data would be provided; Mr. Turer responded that no additional data would be provided but that he was happy to print the tables for the Committee's review

Mr. Hawkins suggested moving forward with voting on the geographic HPSA language, starting with the frontier section and moving on from there. Ms. Sylvester called the question and called for votes moving with the geographic HPSA section as presented in the report.

Dr. McBride asks for clarification regarding the curve and says he cannot support with the language on page 32 – that it won't pass the "smell test" and is unable to explain it himself. Committee members ask him to clarify if this is a philosophical difference versus need for clarification and Dr. McBride explains that he doesn't understand what the model is based on and that he neither liked the curve nor its explanation. Dr. Scanlon agreed that there are a lot of different options for the exponential curve and while the threshold was discussed at length the curve has always been a black box.

Dr. Rarig responded that HRSA in this case could be the determinant as it relates to available resources. The concavity of the curve could be shifted while using the same thresholds to change the sensitivity in the mid-range. Those who are worried about costs can have comments addressed here as it could depend on how HRSA calibrates the curve.

Dr. Scanlon expressed concern about the thresholds, Medicare spending, and the degree of freedom of the curve. He feels that the Committee is giving HRSA cover for the Medicare spending that they wouldn't have on their own and it's not well explained in the text. Dr. McBride agrees with Dr. Scanlon's concerns.

Dr. Vaz asked for clarification regarding the use of Medicare spending in the curve and Mr. Turer explained that Medicare was used as a target for spending in the designated areas. As a result, the curve reflected to some degree the need to reduce the number of areas designated. Dr. Vaz then stated that the curve was, in essence, a function of the Medicare spending and Mr. Turer mentioned that it was not a function of the spending but that the spending was used as a constraint.

Dr. Rarig asked if a target should be identified for the midrange, how that should function and what it should be; Dr. McBride explained that this was his point, they were taking a vote on a black box. He believes that a vote on the graph line with the constraint will go down 24-4. Dr. McDavid was not clear on whether or not this needed to be tied to Medicare. Mr. Turer responded that the designations were raised when it was applied, for same amount of money with fewer providers. Individuals covered went up because the dollars targeted per person covered went down.

Ms. Sylvester asked whether or not the inadequate definition or description of the curve was something that could be worked on or if the group should move on. Committee members disagreed on the best way forward but felt better language was needed.

Mr. Turer further explained that the curve allowed the lower end to stretch to a much lower P2P, and those factors in the middle could then be used to discriminate. In the middle, health status and ability to pay can be used. In other words, the curve was not just based on Medicare but on the desire to give greater weight to poor health status and poverty.

Mr. Salsberg spoke up and asked to clarify between the wording and the conceptual. He did not think that revisiting the technical components will help the Committee understand the model better.

Dr. McBride was grateful for the conversation – that the curve is determined by Medicare spending – but the model needs to be discussed in more depth. Mr. Scanlon clarified that the model doesn't provide much solace to an area not designated, given the high variability in exponential curves. In some respects, it's an issue of order. Thresholds could have been set first, or the curve could have been drawn first. The point is the sensitivity -- people could say "I'm just on the other side, why am I not eligible?"

Dr. Kornblau suggested that the Committee move on, that new language would not change Dr. McBride's opinion. Dr. McBride responded that if wording was provided that explains what was done, it might change people's vote.

Ms. Sylvester proposed to sleep on it and have a brief discussion and vote in the morning.

The meeting was adjourned for the day.

OPENING OF THE MEETING AND AGENDA FOR THE DAY

Ms. Sylvester opened the meeting opened at 9:19 a.m. and observed that Mr. Camacho and Dr. Vaz would be participating over the phone. She summarized for the committee that the day's agenda would begin with a discussion of the HPSA designation eligibility curve, curve, and then turned the floor over to Dr. Rarig to begin the discussion.

DISCUSSION ON THE DESIGN OF THE HPSA ELIGIBILITY CURVE

Dr. Rarig opened with a focus on the role of health status and barriers in determining designation. She observed to the committee that the curve enabled health status and ability to pay to be weighted more heavily as the area approached an adequate capacity of providers. She summarized that mathematical formula was relying on the ratio of a number to itself squared.

In order to make the model more accessible to the public and to those on the committee, Dr. Rarig proposed that the report include the following language to describe the rationale behind the curve:

"For places in the mid-range, as the population to provider ratio improves, approaching what would be considered "adequate capacity" for a healthy population (i.e., moves from 3000:1 toward 1500:1); increasing emphasis will be placed on health status and ability to pay factors in considering designation."

Dr. McBride noted that the language was an improvement but stressed his desire to ensure that the method was justified. He noted that additional explanation would be helpful but emphasized that his larger concern was the justification for choosing that particular curve. In response to clarifying questions, Dr. McBride stated that an appendix would be an appropriate place for these explanations but that both the fit of the curve and the principle behind it need to be justified.

Dr. Phillips questioned what sorts of test would be required to demonstrate validity. He pointed to the face validity of weighting population characteristics over P2P as the lower threshold is approached and questioned what alternative options existed.

Dr. McBride responded that the equation itself was necessary to determine validity and suggested that the committee apply their four operating principles to assess the curve. He stressed overall the importance of justifying and suggested the relevant literature be included in the committee's documentation.

Mr. Salsberg noted that there was no single correct answer and that the committee would have to base their decisions on principle. Dr. Scanlon returned that the government should not be arbitrary, and that it was critical to establish a reasonable basis to justify lack of eligibility for people on the borders of the curve.

Dr. Rarig suggested that the two obvious mathematical options were a straight line and the curve in question, noting that anything in between would require more of a special justification. She stated that

the curve approach currently in use was fairly conservative, taking the people with highest need as reflected by health status and ability to pay. She suggested that HRSA could choose to make the curve less severe over time if it appeared necessary. She stressed her opinion that the model was elegant and easy to explain, noting that it would appear clearer once JSI provided the formula in writing.

Mr. LeClair suggested that the committee hold further discussion until JSI provided additional language.

MUP METHODOLOGY DISCUSSION

Mr. LeClair stated that population HPSA was outstanding and noted the dependence of this designation on the MUP, reminding the committee of the previous day's discussion regarding low income eligibility. He proposed beginning with the MUP discussion and turned the floor back to Dr. Rarig.

Dr. Rarig referred the committee to data provided by Mr. Turer and confirmed that most MUP score assessments fell beyond the regular threshold of 54.33. She stated the sub-committee's opinion that the most appropriate response to this phenomenon would be to create a higher threshold for MUP designation. She suggested a cut-off score between 80 and 90, which would make only those RSAs with a truly high score eligible. She noted that this would allow the variables and approach to remain constant with the other designation strategies.

Mr. Turer noted that the current distribution was based on the assumption that the populations at risk had no different attributes than populations not at risk vis-à-vis P2P and health status. He stressed that the population designation was supposed to drill down on a specific barrier and measure the access to care and health status of that group specifically. He noted that this could create dramatic shifts in scores based on the population in question and stated that, in theory; each population should have its own threshold. Dr. Rarig concurred, stating that designating additional RSAs would create more work for HRSA in processing applications and that it was reasonable to identify only those RSAs and populations with truly high needs.

Mr. Salsberg raised concern about the strategy of using different thresholds for different populations. He noted that the key challenge appeared to be low-income and Medicaid designations and referred the committee to the existing standard requiring low income represent at least 30% of the population before designation could be achieved. He suggested that language addressing either size or percent of the population might be reasonable and offered a second alternative that the applicant exclude the barrier on which the application was based when calculating their overall score.

Mr. Camacho then questioned whether it would be possible for the population to replace the barriers to care variable with a statistic describing the specific issues experienced.

Dr. Wilson noted that statistics or data would back up claims of barriers and concurred with Mr. Salsberg that low income was a particularly tricky population for threshold purposes. She stressed that the sub-committee wanted to keep the focus on populations in need but agreed that relative need was important.

Mr. Camacho summarized his impressions that barriers to care was the primary issue on the table and that, in certain populations, ability to pay caused the scoring to go all the way to the right.

Dr. Larson stressed that including a minimum population number or percentage would cause a huge issue for her constituents, observing that even in the streamlined process a population count would be required. She stated that it was particularly difficult to define a population and offered her support for the RSA language, which allows flexibility in population counts, and would be particularly important for special populations. She suggested that Mr. Salsberg's proposed alternative of requiring a population group to exclude the barrier for which they are applying may also be reasonable, but that additional tests would be required to ascertain the impact.

Dr. Larson then corroborated Mr. Camacho's observation that the true issue appeared to lie with the low income populations and noted that a third approach would be to set a specific threshold for low income. She stated her opinion that justification for this approach was how heavily embedded low income already was in the formula, observing that these populations begin with their application at 40 points, already near the threshold.

Mr. Camacho echoed that there did not appear to be issues with P2P or health status and suggested that the 65% weight accorded to the other two factors have parameters set for the various populations. He provided the example of travel time serving as the only barrier to care for rural low income designations and then summarized that the same criteria would remain in place for low income and ability to pay with an additional barrier added for the local population, in this case, travel time. He observed that this would create a consistent basic framework with flexibility for HRSA regarding additional criteria for special populations.

Mr. Turer provided additional context to the committee, focusing on the distinction between factors and scores and stressed again that the committee consider whether the assumption that the demographic mix is consistent across the special population and the community at large was appropriate.

Dr. Phillips stated his support for focusing on threshold adjustments – with a single threshold for the MUP process – to limit the number of designated areas. Dr. Rarig agreed, stating that while there were several workable alternatives, her opinion was that it should be possible to work within the existing model to identify higher need areas through threshold adjustments. Dr. Wilson concurred, observing that the main goal was to avoid designating 93% of the nation.

Dr. Vaz raised concern that the threshold would be arbitrary. Dr. Rarig countered that all of the thresholds were somewhat arbitrary and stated that while the group could provide conceptual guidance, final designation decisions would be left to HRSA and dependent on available resources. She followed with proposed language that would read as such: "…have a revised threshold for medically underserved populations that would identify the top neediest 1/3 of RSAs for potential eligibility for designation."

Mr. LeClair called for consensus vote on the MUP methodology. Votes were as follows:

- 19 yes votes
- Four abstentions (Mr. Morgan , Dr. Vaz, Dr. McBride, and Mr. Camacho)
- One no (Dr. Scanlon)

Please note for the record that Mr. Camacho later requested to change his vote to a "no," creating the following tally:

- *19 yes votes*
- *Three abstentions (Mr. Morgan , Dr. Vaz, and Dr. McBride)*
- *Two no votes (Dr. Scanlon and Mr. Camacho)*

After a request from the committee to provide a viable alternative strategy, Dr. Scanlon commented that the issue was not that the strategy wasn't viable, but that the current proposal had not been fully explored. He stated that his no vote was an indication that HRSA needs to do additional research to see if there is a better alternative.

Dr. Rarig asked the committee if, procedurally, there was a way to agree on a concept or alternative approach – representing an improvement over the current methodology – and request that HRSA make additional research in that area a priority. She stated that the reality of designating an RSA could mean that HRSA is immediately burdened with processing multiple funding applications from that RSA and referred the committee to the previous example of Montgomery County. She observed that the consequences of the committee's decisions were great, but stated that ideas for improved methods to target resources should be shared with HRSA and prioritized.

Dr. Scanlon responded by focusing on the importance of ensuring that wealthy, resourced counties are not designated due to the risk that their applications could be well put together and very attractive to HRSA in the review process.

Ms. Kornblau suggested that the committee conclude discussions and move on.

In response to a request by Mr. Camacho, Mr. Salsberg clarified that the group could later agree on what the report would show in terms of next steps and suggested these comments could be included in a section of recommendations beyond the rule itself. He noted that the population designation would be an appropriate area for a new advisory committee to explore and suggested that the committee follow Mr. Camacho's recommendation by highlighting this topic as a priority area for new research.

Mr. Camacho questioned whether something could be considered a recommendation if there were no votes on the record. Mr. Salsberg clarified that if consensus was not achieved on the report overall, the Secretary would consider areas of consensus and other recommendations of the committee. He stressed that this had less force than overall consensus and that there was no guarantee of implementation. Dr. Vaz provided additional clarity based on the Negotiated Rule Making Act, citing that "[I]f a committee reaches a consensus on a proposed rule, at the conclusion of negotiations the committee shall transmit to the agency that established the committee a report containing the proposed rule. If the committee does not reach a consensus on a proposed rule, the committee may

transmit to the agency a report specifying any areas in which the committee reached a consensus. The committee may include in a report any other information, recommendations, or materials that the committee considers appropriate. Any committee member may include as an addendum to the report additional information, recommendations, or materials."

Mr. Salsberg moved to the next item on the agenda, which focused on eligibility in the mid-range for the population HPSA. The discussion was tabled to allow Dr. Rarig additional time to develop the rationale. A brief discussion was held regarding the rationale for the curve. Dr. Wilson then noted Mr. Turner's offer to provide additional details over lunch. Mr. Salsberg then turned the floor over to Ms. Kuenning to discuss the EMUP designation.

EMUP DESIGNATION DISCUSSION

Ms. Kuenning provided broad context regarding the EMUP to the committee, noting that while a statute exists for this designation, there are no existing regulations; rather, there are guidelines, which would continue to stand without intervention from the committee. She stated her opinion that it would be valuable for the committee to provide recommendations to ensure that the EMUP process would remain parallel with the new process overall.

Ms. Kuenning directed the committee's attention to her proposed language, which provided a definition for the EMUP and for the service area, guidance for local communities, and a suggested timeline for updating these designations. She noted that the committee had opted not to provide language addressing the Governor's designation/secretary-certified designation beyond stating that it exists. She stated that changes in the most recent draft, sent to the committee after lunch, did not address substantive issues other than the updating process.

Ms. Kuenning stated that the EMUP is an exceptional designation, requiring applicants to first attempt the MUA/MUP process. She noted that this definition was consistent with existing practice.

With regard to the service area, Ms. Kuenning stated that it does not need to relate to the existing RSAs or PCSAs due to unique population boundaries, but stressed that, in order to avoid double counting of the same exceptional population, applicants should not cross or be a subset within the existing RSA. She observed that this was consistent with the committee's work on RSAs. She stated that the guidance provided detail regarding how to demonstrate unusual local conditions and that a few examples were provided for illustration purposes. She stated that the proposed update process would be tied to the decennial census data and suggested that the committee recommend regular updates within one to two years of these data being available.

Dr. Scanlon requested clarification on the number of existing designations and previous denials. Ms. Jordan responded that there are not a huge number of existing designations. She noted that HRSA has denied applications in the past, primarily in cases where bad data were presented or when the applicant was not up to the standard of designation. She shared with the committee her advice to applicants, which stresses that applicants should be able to convince their Governors that their area is the worst place in the state.

Mr. Brooks and Dr. McBride thanked Ms. Kuenning for her work. Mr. Brooks noted that a particularly compelling use of this designation would be in emergency situations such as Hurricane Katrina, and suggested the committee append language to that effect in the report. After a question from Ms. Kuenning, Ms. Jordan noted that there was no formal process for expediting designation in those types of situations but that there was some precedence for it in special circumstances.

The committee then discussed the most reasonable timeline for updating. Mr. Salsberg suggested five year updates given that the American Community Survey (ACS) was largely replacing the decennial census, making data availability less of an issue. Mr. Camacho questioned whether yearly would be more appropriate given the extraordinary circumstances the designation was designated to address and requested an example of a situation warranting EMUP designation.

Ms. Jordan provided the example of a community in which the major employer shuts down, causing huge causes in health care access, income, and insurance. She noted that census data would not pick up on this change and pointed out the limitations of the MUA formula in capturing this circumstance. She stated that the EMUP designation hinges in large part on documenting changes in income or economic status through indicators such as dramatically increased enrollment in school lunch programs, amongst others.

Mr. Brooks emphasized the importance of setting a high bar for this type of designation and expressed his opinion that Ms. Kuenning's work represented a marked improvement over the existing situation. He moved for the adoption of Ms. Kuenning's suggestions. Dr. Wilson seconded.

The committee unanimously approved the EMUP guidelines.

Ms. Kuenning clarified that all of the existing language was in guideline form – not statute – and that the proposed changes would not require any updates to statute.

Mr. LeClair then called a separate vote on timeline for updates, asking for no votes on the proposal of updating every five years. There were zero no votes.

The committee reached consensus on the EMUP recommendations with a five year updating timelines. Mr. LeClair released the group for a break at 10:38 a.m.

DISCUSSION TO DEFINE CONSENSUS AND ADDRESS COMMITTEE NEXT STEPS

The meeting was called back to order at 10:55. The committee discussed the status of decisions made and raised questions regarding the definition of consensus and the relationships of interim votes to votes on the final package.

Mr. Salsberg re-summarized the ground rules for the committee, noting that if consensus on the final package was not achieved, the ground rules state that the Secretary will take into account areas of consensus as well as other recommendations. He emphasized that the record would show votes, and that the pattern of votes may in turn guide how much weight the Secretary gives to each of the recommendations. He posed a question regarding whether abstentions precluded consensus.

Following a question by Dr. Vaz, Mr. Salsberg then clarified the difference between votes on the final package and votes on the individual sections.

Mr. Salsberg then observed that though the committee had discussed producing a minority report or adding additional comments, either option presented a logistical challenge with regard to the 10/31 deadline. He noted that the record would identify areas of concern and suggested that the appendix would be the most appropriate place for committee members to provide additional commentary.

Mr. LeClair provided the opinion of the facilitators that abstention means not in agreement but will not block consensus.

Mr. Camacho raised the example of overall facility designations. He noted that the only area without full consensus was the question regarding county jails. Mr. Brooks suggested that as a free standing item, this type of designation could be considered separately by the Secretary

Mr. Hawkins raised concern with leaving follow- through on the regulation to OMB. He stated a desire to revisit any issues of non-consensus to attempt compromise and noted that this type of conversation could take place after the vote on the final package in the event the final vote was not unanimously to approve.

The committee then provided a series of questions and comments regarding the definition of consensus and the distinction between reaching consensus on the individual recommendations and reaching consensus on the entire report. The committee unanimously agreed to accept the facilitator definition of abstentions, meaning that a vote to abstain did not block consensus. Mr. Salsberg addressed the question of changing the definition of consensus, stating that in his opinion it was not appropriate to change the definition this late in the process.

IMPLEMENTATION DISCUSSION

Mr. Owens directed the committee members' attention to page 44 in the document, discussing implementation by state entities and PCOs. He raised the issue of developing communications and messaging for the committee members. He stated that training and funding for training would be critical, noting that regional meetings might reduce the travel and funding required. He also described the committee's position on potential designations, stating that HRSA was requested to prepare a list of potential designations for PCO review, which they could then revise and resubmit. He called for questions.

Ms. Nickerson suggested that RHCs be added to the list of organizations involved in implementation. Dr. Larson then suggested expanding the language addressing applications outside the "potential designation" designation process to clarify the flexibility available to an applicant rather than implying that the PCO was the only possible application recipient.

The committee then discussed the 25% annual review standard. Mr. Salsberg raised concern that this strategy could create a large bolus of work for the PCOs when the initial new round of designations came up for review in four years. Mr. Owens clarified that the roll out of the initial designations would

be sweeping, and that many of the designations would need PCO intervention, which would diminish the number of designations on the exact same review cycle. Mr. Holloway noted that the objective of this strategy would be to even out the workload for PCOs and suggested that efforts be made to even out the arc of the four years, with recently updated existing designations pushed to a later update.

Mr. Salsberg provided a summary of his impression of the implementation strategy, stating that HRSA would use national data to do a blanket assessment and designation – designating up to 2000 HPSAs or RSAs on Sept 30 2012 – with subsequent revision and clarification by the PCO. Ms. Jordan clarified that the while HRSA would run the data, these data and the results would be shared preemptively with the states to ensure that they were accurate and to allow for changes in RSAs, etc. prior to final designation. Mr. Owens concurred with this based on his experience and stated that a PCO's responsibility was to provide HRSA with more recent data and help identify incorrect designation (among other things).

Mr. Salsberg reiterated his opinion that 25% per year could present a challenge.

He then suggested that the committee review Dr. Phillips's proposed language on regular national updates before finalizing their decisions regarding PCO updates. He directed the committee to page 8 of the summary sheet.

Dr. Phillips summarized the language addressing national updates, stating that every five years HRSA should undertake an expedited review (as opposed to a full NRM assembly) to focus on scaling and adjustments to weighting. He noted that this should be subject to public comment to capture experiences with the new rule's roll out. He further suggested that every 10 years a more thorough review should be undertaken and that data should be regularly updated, with updates accompanied by some form of public notice.

Mr. Salsberg questioned whether the committee's recommendations should incorporate a suggestion for re-running the blanket national assessments. Dr. Phillips stated his opinion that national assessments should be redone at the five and ten year marks but requested input from the PCOs on this suggestion. Mr. Holloway commented that PCOs were not really using national data for this rule – that the PCOs responsibility is more focused on high quality local data – but agreed that 5/10 years was a good benchmark for changing the process overall.

The committee agreed that 10 years was a good benchmark to review the process. Dr. Rarig provided additional commentary, noting that the current committee's charge to re-examine the entire rule was somewhat cumbersome. She suggested that interim adjustments would be valuable to avoid future committees facing a similar challenge. She proposed that a 10 year review with an advisory group would be advisable, with PCOs and PCAs responsible for identifying agenda items on a rolling basis. She stated that ten year updates were likely more achievable than five year updates and suggested that there be an alternative process for smaller adjustments in the interim. Dr. Wilson then expressed support for an expedited process every five years with a full review every ten.

A vote was taken on Dr. Phillips's proposed updating language. The committee voted unanimously to accept his proposal.

POPULATION HPSA DISCUSSION

Mr. Salsberg opened discussions on the population HPSA, noting that the key question on the table for the committee was how to address qualifications in the mid-range, particularly with regard to the weighting of health status and poverty in low income designations.

Dr. Rarig reminded the committee that the HPSA designation hinges primarily on P2P and that presumably the low income population HPSAs have a P2P worse than 3000:1.

Dr. Larson noted that the RSA language in the population HPSA section should also be incorporated into the MUP section and Dr. Wilson noted areas of inconsistent language for editing purposes.

Mr. Salsberg returned to the question of weighting in the mid-range and summarized that the options on the table, including evaluating a combination of health status and poverty in the mid-range or using only health status as a factor given the concerns expressed earlier associated with low income designations. He referred the committee to previous analysis implying that low income scoring was a much more serious problem for the MUP than the population HPSA. Dr. Rarig expressed support for the first option (combination of health status and poverty), and Mr. Salsberg called for a vote on the population HPSA as written.

Votes were as follows:

- 21 yes votes
- One no vote (Dr. Scanlon)
- One abstention (Dr. McBride)

TRANSMITTAL LETTER TO THE SECRETARY

The meeting reconvened at 1:38 p.m. Mr. Salsberg read the contents of the transmittal letter to the Secretary aloud. Committee members were asked to sign the cover sheet.

GEOGRAPHIC HPSA DISCUSSION

Mr. Salsberg outlined next steps for the committee, including discussion regarding the geographic HPSA and the eligibility curve, severability, guidance to HRSA overall and issues beyond the rule, minutes, and close out activities. He then opened discussion on the geographic HPSA. He outlined that the current thresholds of 1500 and 3000, and the 1500:1 for frontier area. He stated that the question on the table was what to do with the mid-range of eligibility and asked Mr. Turer to provide a strategy to describe the curve.

Mr. Turer stated that the committee could include a scoring table that showed the threshold at various levels between low and high with a cutoff of 80 and with formulas in a footnote. He provided the following language to describe the curve: "The curve sets the threshold for Health and ATP in the

midrange at the square of the area's P2P, expressed as the inverse of its percent of the range between the high and the low thresholds, divided by the square of the maximum score of 80 corrected for a 100 point scale."

Dr. Scanlon stated that the critical question was the impact of the curve's placement and the rationale for why it was placed where it was. He emphasized that the analysis was not yet developed enough and that the committee needed to be able to show that their decision was not arbitrary, particularly for areas that were on the cusp of eligibility.

Dr. Rarig responded that the key issues were to demonstrate reasonableness and fairness in accordance with the intent of the group. She noted that if you asked statisticians how to achieve the goal you described, they would probably propose this type of curve or something like it. Dr. Kornblau said she was okay with the curve as is. Dr. Scanlon reiterated that areas just outside the curve would want explanations for why the two variables were chosen and how the index was determined.

Mr. Salsberg stated his opinion that there was no perfect formula and that the approach proposed achieved the goals of the committee. He stressed that the proposed option was vastly better than the current "cliff" at 3500/3000, with only one adjustment allowed for high infant mortality or poverty. He stated his opinion that even with ten experts in the room, there would be no definitive answer on how best to draw the curve.

Dr. Scanlon replied that analysis to justify the curve was necessary and that it was critical the government not make arbitrary decisions. It may be qualitatively correct but not quantitatively correct; wearing his GAO hat he had to ask "What did the committee do and what were the results?" Dr. McBride concurred that the committee had not adequately addressed why they selected this particular curve and not others-"we like it" is not an adequate reason; he noted that the evidence and literature base to defend their decision was not specified.

Ms. Nickerson noted that the curve was not just based on "we just like it", but is in part based on the decision of those working on the ground, and stressed the inclusion of factors important to HRSA in making a more nuanced eligibility decision. She expressed her opinion that Mr. Turer had provided an explanation and that it was not necessary for the committee to fully understand the statistical detail in order to make an informed decision.

Dr. Taylor asked Dr. Scanlon how he would "test the curve". He also stated that since there was no gold standard answer, it was critical for the committee to triangulate their actions. He stated that the committee's key responsibility was to achieve consensus where they could and lay out a process for the government to address areas of uncertainty and move on.

Dr. Phillips reminded the committee that this issue first arose early in the process with a goal to get away from the current cliff and incorporate population health measures. He noted that the committee was held to hard numbers regarding the spending associated with geographic HPSAs and that this in turn affected the placement of the line. He stated that the line was not arbitrary, as it was based on population risk factors, a lower threshold to pull in more geography lacking access, and available dollars.

He expressed his opinion that the proposed curve was the best fit for the existing parameters and expressed hope that the committee could move forward with the proposal. He suggested that if the committee couldn't move forward with the specific curve, a compromise would be to achieve consensus on the need for a curve and provide a framework for HRSA without specifying a shape. He continued on to urge that the committee be as specific as possible in their recommendations.

Mr. Brooks agreed with Dr. Phillips and emphasized that the curve was based on the collective work of the committee to date. He noted that the previous minutes would reflect the critical decision points in designing the curve.

Ms. Kuenning added that that the original process had required HRSA to make a determination that 62 was the cutoff for the current MUA process (it was the median score of the counties at the time of regulations were developed) and that the current committee was always going to have to make decisions that qualified and/or disqualified particular areas. She stated her opinion that the current document provided a conceptual framework to HRSA with as much evidence as possible while allowing HRSA the ability to do further analysis in order to refine. She questioned why this did not fit Drs. Scanlon and McBride's specifications.

Dr. Scanlon stated that he did not object to the concept, but that he did not believe that HRSA could definitively say that this particular curve as drawn was absolutely the curve that should be adopted. He stressed that the committee should be working to provide HRSA protection and a reasonable defense for designation decisions.

Ms. Kuenning commented that, as HRSA's representative, Mr. Salsberg's accord implied that HRSA felt adequately protected. Mr. Salsberg suggested that the committee could provide HRSA the impetus to move forward and do the work rather than not move forward at all.

Dr. Scanlon expressed his belief that the justification provided would not stand up to public scrutiny.

Mr. Brooks noted that while he was not in substantial disagreement with Dr. Scanlon, he did not feel that the inclusion of the curve as a conceptual framework did significant damage to the report and that he could support the proposal if it would get them to consensus. Ms. Nickerson followed that, given the expertise of the people on the committee, she was unsure that HRSA would necessarily make any better decisions.

Mr. Camacho requested that Drs. Scanlon and McBride provide context for the specific steps that would be required for them to feel that the curve had passed the "reasonableness" test.

Dr. McBride responded that the existing evidence base was weak. Dr. Scanlon expanded on this to suggest that the analysis to determine the reasonableness would involve comparing those who are being excluded to those included and examining the borders of the curve to amass evidence that there was not an arbitrary distinction between the two categories. He noted that the current curve could create a situation where a community with a P2P of 2700:1 was excluded but a community with a P2P of 1600:1 was included and suggested that this would be an opportunity for complaint.

Ms. Kornblau provided perspective on the charge of the committee based on her experience with NIH consensus conferences and stressed that everyone at the table brought an expertise to the group. She emphasized that the proposed curve was put together on a consensus of experts.

Mr. Holloway observed that while half of the report was likely to acquire universal consensus, the other half was likely to have dissent to varying degrees. He noted the committee's fairly broad appreciation that not every decision would be fully supported and suggested that the report include the following language to indicate a stepwise process. He proposed that:

1. HRSA include all areas with consensus in the report
2. Areas that have full consensus be adopted
3. Parts of the rule where consensus is not reached be identified and separately addressed by HRSA in partnership with a small advisory committee

Mr. Holloway suggested that this might allow much of the committee's work to become law while also allowing flexibility to HRSA in further developing certain sections.

Dr. Taylor summarized the comments, saying that in his opinion, if the committee proposed an analysis that carefully examined the characteristics of communities on either side of the line and specified specific and technical questions for HRSA to explore, that this may enable them to create a report that all members could sign off on.

Dr. Vaz agreed that justification was lacking but stated that a report that did not bind the committee to a formula would be an option. Ms. Hirota raised concern that Dr. Vaz's absence from some of the previous deliberations may hinder his full understanding of the rationale behind the curve and stated her opinion that the committee's work was on track. She expressed her preference for the presentation of a conceptual framework that would for allow adaptation and additional analysis. Dr. Vaz responded by saying that he was, in fact, present when the curve was first introduced and had subsequently followed up on all discussions and that he understood fully the rationale behind the curve and that he would like the record to reflect this.

Ms. Kuenning in turn proposed that the report include language indicating that, for those sections where consensus did not exist but substantial agreement has been found, the Secretary should recognize that agreement and afford it the appropriate weight. She expressed support for Mr. Holloway's proposal of viewing the report section by section and of clarifying the definition of abstention.

Mr. Brooks made a motion to accept the curve construct as a conceptual framework that would require vetting along the edge of the curve by HRSA as the will of the Committee.

Ms. Sylvester called for a vote on the conceptual framework of the curve, the suggestion that the Secretary consider the weight of each vote, and the existence of a smaller HRSA advisory committee to consider the outstanding issues.

Dr. McBride questioned how it was possible to vote on the conceptual framework of the curve. Dr. Rarig responded that this could summarize the intent of the committee, which was to improve upon the current cliff for eligibility and to take into account health status and ATP in a simplified assessment that relies only on those two variables. She observed that the distribution of communities was known and could be further explored.

The vote was called on the conceptual framework. The votes stood as follows:

- 22 yes votes; one abstention (Dr. McBride)

Ms. Kuenning then provided proposed language to address areas of non-consensus, the language was as follows: "The Committee strongly encourages for those sections which consensus does not exist, but substantial agreement is evident, the Secretary will consider the recommendations of the Committee, providing it with the appropriate weight based on the Committee's role."

A vote was called on this language. The votes stood as follows:

- 23 yes

A vote was called on Mr. Holloway's recommendation for the creation of an Advisory Committee. The votes stood as follows:

- 23 yes

Mr. Camacho suggested that it would be helpful if Drs. Scanlon and McBride could provide specifics in writing to assist HRSA with the additional analysis. Dr. Scanlon responded that he and Dr. McBride had discussed the possibility of drafting an appendix to the report.

Mr. Salsberg made a motion to approve the language regarding geographic HPSAs with the curve revision as discussed discussed. The votes stood as follows:

- 21 yes votes
- 2 no votes (Drs. Scanlon and McBride)

DISCUSSION REGARDING STRATEGY FOR PROVIDER BACK-OUTS

Dr. Scanlon raised the issue of provider back-outs and the yo-yo effect. Mr. Salsberg suggested that this would require a return to the P2P discussion. Mr. Hawkins noted that this issue had arisen in both the P2P and geographic HPSA sections.

Mr. Camacho suggested that the committee start from the premise that proposed language did not constitute a recommendation if consensus was not achieved. He suggested that the group use Ms. Kuenning's language to back off calling the provider back-outs a recommendation per se, but still include the suggested groups in an appendix. He suggested that the phrasing could be similar to: "the Committee, in departure from current policy and practice, recommended excluding {list of provider types……}. However, no consensus was reached given the disagreement concerning whether including

these providers in the provider count could result in a yo-yo effect, in which an area {is designated due to the back-out and then would be de-designated once those providers are included}. Therefore, the Committee requests that HRSA put {recommendations for additional analysis}. ”

After a question from Ms. Kuenning, Mr. Camacho clarified that he was suggesting the language address the discussion and note that there was disagreement on the existence of the yo-yo effect. He stated that the report should indicate that the committee did not reach consensus because of that disagreement and should outline steps for HRSA to take to document the presence/absence of a yo-yo effect.

Dr. McBride provided the following proposed language for the committee’s consideration:

"In a departure from current policy and practice, the Committee also recommends excluding National Health Service Corps Scholars and Loan Repayment recipients, State Loan Repayment Program (SLRP) recipients and providers who work at HRSA grant-funded health centers, FQHC look-alikes, and hospital-based or independent RHCs that accept patients regardless of ability to pay, if data are available. The Committee discussed concerns about the possibility there is a "yo-yo" effect of including these providers in the provider count in which an area is designated as underserved ("yo-yo effect" defined as: an intervention occurs as a result of the designation; the newly placed practitioners are counted and result in a loss of designation; the intervention is removed; and the area again becomes eligible for designation). Therefore, the committee recommends that HRSA sponsor research in this area to consider this issue further."

Mr. Camacho requested that the language address the specific research requested, which would be to study how the back-outs affect designations. Dr. Scanlon proposed that the research be specific to each individual back-out category.

Mr. Salsberg noted that the back-outs as proposed included a relatively large number of programs and expressed concern that the guidance as written was vague. He asked whether the committee would be comfortable with the guidance that HRSA should assess the back-out/yo-yo effect of including several categories of federal practitioners and, if it determines that there is a yo-yo effect that HRSA should back out that particular provider category. He noted that this would give HRSA the leeway to say yes to some groups and no to others while maintaining the option to say yes or no overall.

Mr. Morgan asked for clarification on whether this language was intended to imply that no providers be backed out unless HRSA found it appropriate. He noted that the initial back out was essential for his support of the proposal and he did not favor further study. Mr. Salsberg clarified that there would be some initial back out but that more in-depth analysis would be required. He suggested that one possibility would be to identify two or three categories where the committee anticipated serious consequences of not backing out and then allow HRSA’s research to determine if a greater back-out would be warranted.

Dr. Scanlon questioned whether the committee was operating on the basis of assumption or analysis and commented that the former approach would require a no vote from him. He noted his observation

that there was an interest in publishing the rule within a certain time frame and suggested that, given the difficulty of establishing inclusion vs. exclusion, the group should adopt Ms. Kuenning's language allowing the Secretary to take the committee's votes into account and do what is best.

Ms. Kuenning stated her understanding that the hope was the proposed language change would address the concerns of Drs. Scanlon and McBride and thus allow a consensus "yes" vote on the whole package. She stated her opinion that if Dr. Scanlon could not vote yes on the package, there was no need to make these types of concessions in the interim.

Dr. Scanlon stated strongly that he would not be able to vote yes and noted that the MUA in particular caused him to have irreconcilable doubts. He stated that the previous day's discussion led him to become more and more convinced that on many different points the evidence to go forward was lacking and that the rule was not ready for publication. He noted that the committee had developed plenty of insight and information but stressed that HRSA should do additional research to finalize the rule.

A vote was called. The committee decided to let the existing Workforce Committee recommendation of back out prevail, and not to move forward with Dr. McBride's proposed changes.

RSA AND THRESHOLD DISCUSSION

Mr. Salsberg asked for an updated report on the RSA. Mr. Holloway noted that language refinements were pending but that he would ask for an approval of the section. Mr. Holloway also observed that the group could reopen debate on the threshold of 2000/1 for overutilization of contiguous areas adjacent to the RSAs.

Dr. Larson called for a vote on the threshold of 2000/1 and then a separate vote on the RSA proposal. The votes stood as follows:

- 2000/1 threshold
  - 21 yes
  - 2 abstentions
- Overall RSA
  - 22 yes

SEVERABILITY LANGUAGE DISCUSSION

Mr. Salsberg summarized outstanding issues before the committee, including the curve for MUAs, issues to include in the report, review of the minutes, and obtaining committee members' signatures for a cover letter on the report to the Secretary. He then opened discussion on additional issues to include in the report, turning the floor to Ms. Kuenning to discuss severability language.

Ms. Kuenning noted that the ground rules for the committee do address severability but suggested that the following language be included in the report to strengthen the committee's recommendations: "The committee intends the separate sections of this report to be severable so that those sections for which

consensus was not reached will be severed from the whole and the remaining sections will remain in full force and effect and binding upon the Secretary as if the severed provisions do not exist."

Mr. Salsberg expressed concern with the framing of the language, stating his belief that the committee could not bind the Secretary to accepting any of the provisions in the absence of the full acceptance. He stated his opinion that the existing severability language was directed more toward illegal provisions than non-consensus areas and suggested the committee focus their severability language on any provisions found to be contrary to the statute.

Dr. Clanon commented that the statutory language did not, in her opinion, specifically preclude the idea of consensus in part.

Mr. Salsberg responded that there were two places the committee should review to come to a determination on severability: the Federal Register notice as well as the rules for negotiated rule making. He read aloud the severability language from negotiated rule making statute and asked the committee to remember that those rules guided their process. Dr. Clanon offered to research further in an attempt to reconcile the two.

The committee then debated whether the discrete areas of the report could be considered self-contained and, if so, how that impacted the agreement the committee members made not to comment on the final rule in the event of consensus. The group did not reach agreement on this issue; Ms. Kuenning expressed her opinion that committee members were held not to comment on any areas of consensus while Mr. Morgan stated his belief that if total consensus on the full package was not reached the members should be allowed to comment.

Ms. Sylvester suggested that the committee rely on the terms of the original agreement; copies of the ground rules were passed out to committee members.

The committee continued to debate the definition of consensus and whether the preparation of a report by definition meant that consensus was not achieved. Ms. Sylvester reminded the committee that their goal was to prepare an interim final rule, and read from the ground rules the process for identifying areas of consensus if overall consensus was not reached.

Ms. Kuenning then noted that, according to the ground rules, unless consensus was achieved on the full package, the areas where the committee did achieve consensus would not be binding. She stated that her language was intended to make areas of consensus binding while allowing the Secretary to make adjustments to any areas without consensus.

Mr. Brooks provided his opinion that it was not possible to bind the Secretary without full consensus; Mr. Holloway in turn agreed with Ms. Kuenning that the "binding" language was unclear and could be interpreted to apply to the entire report or the sections individually. Ms. Kuenning restated her goal of retaining the work done by the committee to achieve consensus on the subsections; Mr. Brooks noted that he had no problem voting for the language.

The committee took a break.

AMERICAN COMMUNITY SURVEY (ACS) DISCUSSION

Mr. Salsberg brought the committee back to order. He noted that the previous severability discussion was not resolved but urged the committee to first focus on the final report and the ACS. Dr. Larson opened discussion on the ACS by orienting the committee to the document in front of them and turned the floor over to Dr. Rarig to discuss the minor adjustments made.

Dr. Rarig outlined the following key points:

1. The committee should suggest that any use of the ACS data in the designation process rely on the five year estimates for all geographies as only the largest RSA would have data from a single year or three year data.
2. Given concern regarding the accuracy of the point estimate for very small populations, the committee should suggest that applicants be allowed to use the upper limit of the 80% confidence interval for their determination. She also called attention to a correction made at the bottom of the note, stating that the 10% previously used had been updated to 5%. She then reiterated that if the error estimates were less than 5%, the applicant should be permitted to use the upper limit of the 80% confidence interval.
3. The committee should request for ASAPs to include data to assist applicants with recalculating the 90% and 80% confidence intervals.
4. There were no changes to the language indicating that HRSA should develop the standard set of tables for ACS.
5. The committee should suggest that HRSA work with the census bureau to provide ACS data required by the designation process and by appropriate geography for public use. Dr. Rarig noted that the current census reporting system doesn't provide data aggregations by RSA but that this information would be very helpful for applicants. She then noted that the Census Bureau was planning to have a form online for requests for new geographies, which would enable this type of programming. She noted that several other bodies created by the ACA were planning to make similar requests and stated her opinion that both the costs and maintenance associated with this request should be reasonable.

Dr. McBride questioned whether using the five year roll-ups would unnecessarily add error – by virtue of older data – to the score calculation for larger areas. Dr. Rarig responded that hardly any of the areas big enough to have one year data are RSAs and reiterated that very few RSAs would have one or even three year data available. She then shared the Census Bureau's recommendation that whenever ACS data are used to compare areas of different sizes the same time period should be employed for all areas.

Dr. Scanlon raised the question of the magnitude of score adjustment that would result from using the bottom of the confidence interval to calculate scores, noting that this was really a function of sample size.

Dr. Rarig responded that this issue wasn't very relevant except for very small areas and that she estimated the impact to be small. Dr. Larson commented that this strategy was meant to equalize information from a competition perspective by providing assistance to areas with a large margin of

error. She noted that the committee had tried several strategies and had collaborated with the Census Bureau on their approach. Dr. Rarig added that this would likely become a non-issue if the Census Bureau were able to produce data by the specifically requested geographies due to the roll-up of data.

Mr. Turer then commented that using the five year roll-up was more appropriate as it allowed for a more consistent effect of macro-economic issues, using the impact of the recession as his example. He also noted is that some of the confidence intervals can be quite large. Dr. Rarig added that even large RSAs are not necessarily consistent with the areas for which the Census Bureau collects data; Mr. Turer concurred, noting that only the RSAs that are counties would align with Census Bureau collection. Dr. Larson then provided Census Bureau estimates that 42% of all counties have no any one year estimates.

Ms. Sylvester called for a vote on the ACS recommendations. The committee unanimously approved.

DISCUSSION REGARDING GUIDANCE TO HRSA ON RESOURCE ALLOCATION

Mr. Salsberg opened discussion, stating that the committee may wish to consider providing greater guidance to HRSA on how best to allocate resources. He noted that he had shared proposed language with the committee and that he had received modifications to that language. He suggested beginning discussions with the rationale for guidance on resource allocation before moving to specific wording.

The committee broadly concurred with the sentiment that, in light of the fact that there would likely always be more designations than federal resources should support, resources should be targeted on need, observing that this was likely more of an affirmation than a new expectation. The committee then noted that individual applications would be evaluated both on quality and relative need and clarified that this language was not intended to imply that resources would be taken away from current existing recipients but rather would focus new resources on areas of most significant need.

Dr. Wilson and Ms. Kuenning commented that additional clarity was needed. Mr. Camacho raised as question regarding the committee's authority to provide guidance in this area.

Mr. Salsberg responded that this language should be considered guidance and go into the report rather than the regulation. He reminded the committee that based on the population covered by the new designations, the application process would be competitive and stated that though the targeting of resources to highest need areas was likely already occurring, the committee should consider putting their advice to this effect in writing.

In response to Mr. Camacho's question regarding authority, the consensus of the committee was that inappropriate language would be severed by the Secretary/OMB if necessary. After additional discussion Mr. Salsberg reiterated that this would be in the report rather than the rule – thus, non-binding – and the committee would simply be urging HRSA to consider need in the allocation of resources. Ms. Kuenning proposes language that supports resource allocation, recognizing that it be focused on a portion of new funds, and not reflects intent that existing funding, or all new funding be targeted to the most severe needs. Mr. Salsberg and Ms. Kuenning agreed to draft language for the report regarding resource allocation.

Ms. Sylvester called for a vote on the language in question. The committee unanimously approved its inclusion with 23 yes votes.

PUBLIC COMMENT

Ms. Sylvester asked the audience for public comment. One letter was circulated but there were no public comments at the meeting.

ADDITIONAL DISCUSSION REGARDING SEVERABILITY

Mr. Salsberg brought the conversation back to severability, noting that the committee needed to vote on the overall package and then address issues regarding consensus or non-consensus. Ms. Kuenning then summarized for the committee her proposed language, noting that it was intended to ensure that the work done by the committee to gain consensus on small segments would result in those pieces being accepted by the Secretary.

Mr. Hawkins broke the proposed language down into three interrelated section:

1. That the committee intends the separate sections to be severable,
2. such that those sections for which consensus was reached shall be implemented by the Secretary,
3. While any sections for which consensus was not reached should be considered by the Secretary taking into account the vote of the Committee for each such section,
4. and any recommendations found to violate law or HRSA's legal obligations shall be severed from the whole and the remaining sections will remain in full force and effect as if the severed sections do not exist

Ms. Kuenning then provided the following summary language for the committee's review and vote:

"The Committee intends the separate sections of this report to be severable so that those sections for which consensus WAS REACHED SHALL BE IMPLEMENTED BY THE SECRETARY AS RECOMMENDED BY THE COMMITTEE, WHILE THOSE SECTIONS FOR WHICH CONSENSUS was not reached MAY BE CONSIDERED BY THE SECRETARY, TAKING INTO ACCOUNT THE VOTE IN THE COMMITTEE FOR EACH SUCH SECTION. IF ANY OF THE COMMITTEE'S RECOMMENDATIONS ARE FOUND TO VIOLATE FEDERAL LAW OR HRSA'S LEGAL OBLIGATIONS, THOSE RECOMMENDATIONS SHALL be severed from the whole and the remaining sections will remain in full force and effect as if the severed provisions do not exist."

Mr. Salsberg stated that guidance from counsel may be required and again raised concern about the strength of the language used, stating that he was uncomfortable suggesting that the Secretary "shall" implement any of the committee's recommendations in the absence of full consensus. Dr. Scanlon concurred, questioning the committee's authority to direct the Secretary's actions.

Ms. Kornblau suggested that using "strongly recommends" or "strongly urges" in lieu of "shall" would be more appropriate. Mr. Hawkins noted that if the committee had reached consensus, their

recommendations would be binding; Dr. Scanlon countered that if they had reached consensus, their authority would be coming from Congress. Dr. Scanlon supported the use of "strongly urges."

Ms. Sylvester directed the committee's attention to the existing language of "will give weight" and questioned whether this accomplished the committee's goals with the proposed language. After a few minutes of additional discussion, the committee settled on the use of "strongly urge" in lieu of "shall" in Ms. Kuenning's proposed language.

A formal vote was called. The votes were as follows:

- 21 yes votes
- One abstention (Dr. Vaz)

Dr. Phillips was out of the room and unable to vote.

Mr. Camacho questioned whether the practical implication of the severability language developed was to enable committee members to vote yes for the report while preserving any no votes against particular sections of the report. The committee generally agreed that this was their intent. Mr. Salsberg then offered to provide a summary of the votes taken to that point.

SUMMARY VOTE TALLY AND PREPARATION FOR FINAL PACKAGE VOTES

Mr. Salsberg provided the following summary of votes taken across the course of the meeting to that point:

- Introduction of the report
  - Unanimous agreement
- Conceptual framework for the report:
  - Overall
    - 22 yes votes
    - One abstention
  - Recommended additional language regarding weight accorded to the Committee's recommendations in areas of non-consensus – unanimous
    - 23 yes votes
    - Zero no votes or abstentions
  - Proposal of a small advisory committee to work with HRSA – unanimous
    - 23 yes votes
    - Zero no votes or abstentions
- RSA language
  - 2000/1 threshold
    - 21 yes
    - 2 abstentions
  - Overall RSA
    - 22 yes

- Calculation of P2P as a whole
    - 18 yes votes
    - 3 no votes
- MUA methodology
    - 16 yes votes
    - 2 no votes
    - 2 abstentions
- MUP methodology
    - Original vote:
        - 18 yes votes
        - One no vote
        - 44 abstentions
    - Jose requested his abstention be updated to a "no"; final vote tallies are thus:
        - 18 yes votes
        - 2 no votes
        - 33 abstentions
- HPSA geographic methodology
    - Provider back-out (vote taken 10/1-further discussion did not ultimately change the recommendation)
        - 16 yes votes
        - 4 no votes
    - Methodology overall
        - 21 yes votes
        - 2 no votes
- HPSA population designation
    - 21 yes votes
    - 1 no vote
    - 1 abstention
- Facility vote
    - County correctional facilities
        - 15 yes votes
        - 5 no votes
    - Facility designation overall
        - 18 yes votes
        - 0 no votes
        - 2 abstentions
- Severability language
    - 21 yes votes
    - 0 no votes
    - 1 abstention
    - 1 member out of the room

- EMUP designation
    - Five year updates
        - 100% consensus
    - Process overall
        - 100% consensus
- Implementation Proposal with Dr. Phillips timeline/updating process
    - 100% consensus
- Proposed ACS recommendations
    - 100% consensus
- Guidance to HRSA regarding allocation of resources based on need
    - 100% consensus

Though not included in Mr. Salsberg's original tally, the committee also took separate votes on:

- The definition of a vote to abstain
    - Unanimously approved the facilitator-offered definition that an abstention indicated a lack of agreement but would not block consensus

- Ms. Kuenning's Language on urging the Secretary to consider areas of non-consensus
    - 100% consensus
- Formation of an Advisory Committee to help HRSA with further research and analysis
    - 100% consensus

    Unanimously approved the facilitator-offered definition that an abstention indicated a lack of agreement but would not block consensus

- Dr. Phillips's suggested implementation timeline/updating process
    - Unanimously approved
- Proposed ACS recommendations
    - Unanimously approved
- Guidance to HRSA regarding allocation of resources based on need
    - Unanimously approved with 23 yes votes

Dr. Clanon raised again the question of whether or not it was possible to vote yes on the whole package while preserving negative votes for the subsections, questioning whether the severability language would then allow the sub-elements with consensus to go into the rule while those without consensus would be excised. Dr. Rarig then raised the question of whether those objecting would be required to spell out their reasons for disagreement. Mr. Salsberg commented that objections had been recorded in the minutes and would be included in the report.

Mr. Brooks made a final plea for unity. He asked the committee members to appeal to the better angels of their nature to send to the Secretary an admittedly imperfect document, but one that in his opinion probably passed the 70% test. He asked the committee to consider the underserved and those that they

were representing. He asked the committee to consider whether a no vote would truly accomplish what they were intending to express, and expressed his opinion that a yes vote with an explanation of the areas of disagreement would be far more helpful to HRSA and to the nation than a no vote. He asked the committee members to please engage in introspection to weigh the impact of their votes and to attempt to get to yes.

Mr. Camacho questioned whether a yes vote would prevent an individual from commenting on sections (s)he disagreed with. Mr. Salsberg responded that the answer would depend on what Mr. Camacho meant by commenting and stated that members were free to add comments to the report. He added that in the event of consensus on the full rule the committee members were bound by their agreement not to speak out against any of the provisions.

Mr. Camacho rephrased his question to specifically ask whether his vote on the full report voided his negative comments on the individual sections. Dr. Wilson responded that the issue at hand was consensus: that if the committee reached full consensus no member could comment during the open comment period, but that if any one member of the committee voted no against the package then consensus would not be reached and all members could make public comments.

The key question at hand was whether achieving consensus on the full package obviated the committee members' ability to provide comments. Dr. Scanlon commented that the committee appeared to be discussing two different sets of comments simultaneously and stated his opinion that if the committee reached consensus, no member of the committee could comment negatively on HRSA's published rule. He followed to observe that that was very different from commenting on the contents of the report.

Dr. Scanlon then summarized his position for the committee. He stated that while he was very much concerned about the populations in need, a part of his concern was how to insure that the limited resources were directed to the neediest individuals. He stated that his comments in the report regarding his areas of disagreement would hopefully indicate to the Secretary and to HRSA areas where improvements were possible in the allocation component of the designation process. He stated his sense that if he were to vote yes to the report, HRSA and the Secretary would be unable to do any additional analyses not specified in the report. He stated that the committee hadn't touched on some of the core issues and that, for these reasons, he would be voting no.

VOTE ON THE FINAL PACKAGE

Ms. Sylvester called for an up or down vote on the full package. The votes, by name, were as follows:

- Dr. Babitz: Not present
- Dr. Brassard: Yes
- Mr. Brooks: Yes
- Mr. Camacho: Yes
- Dr. Clanon: Yes
- Ms. Giesting: Not present
- Dr. Goodman: Not present

- Mr. Hawkins: Yes
- Ms. Hirota: Yes
- Mr. Holloway : Yes
- Dr. Kornblau: Yes
- Ms. Kuenning: Yes
- Ms. Lamoureux: Not present
- Dr. Larson: Yes
- Dr. McBride: No
- Dr. McDavid: Yes
- Mr. Morgan: Yes
- Ms. Nickerson: Yes
- Mr. Owens: Yes
- Dr. Phillips: Yes
- Dr. Rarig: Yes
- Dr. Rock: Not present
- Mr. Salsberg: Yes
- Dr. Scanlon: No
- Ms. Smith: Yes
- Dr. Vaz: Yes
- Dr. Taylor: Yes
- Dr. Wilson: Yes

The final vote tally was as follows:

- 21 yes votes
- 2 no votes (Drs. Scanlon and McBride)
- 5 not present (Dr. Goodman, Dr. Babitz, Ms. Lamoureux, Ms. Giesting, Dr. Rock)

DISCUSSION REGARDING SEPTEMBER MEETING MINUTES

The majority of the committee had not yet finished reviewing the minutes. Mr. Salsberg stated that HRSA staff would continue to accept comments on these minutes and that, given the critical nature of the decisions made in the last two days of the meeting, he would prefer committee members take their time reviewing and responding to the minutes. He requested that comments be provided by Monday.

CONCLUDING REMARKS AND NEXT STEPS

Mr. Salsberg continued discussion on next steps for the committee, listing the outstanding steps and tentative timeline as follows:

- Committee members should send their comments on the September meeting minutes to HRSA for incorporation
- Minutes from the current meeting would be shared as soon as possible

- The full report would be revised and shared with the committee shortly. He requested that those thinking of submitting comments bear in mind the October 31 deadline and stated that HRSA would obtain comment on whether this was a firm deadline.

Mr. Salsberg then thanked the committee for their tremendous amount of work and dedication. He emphasized that while direct democracy was difficult and that the timeline of the rule was uncertain, he was sure that the work of the committee would have a very significant impact on HRSA and would provide great value to the nation. He stated that he would miss the committee and that he looked forward to working with each of the members in the future.

Dr. Clanon raised two practical comments. The first was how committee members could best keep in touch with the subsequent elements of the process, such as the selection of advisory committees and the Secretary's progress on the rule. She then asked that the group share any white papers or PowerPoint slides they develop.

Ms. Jordan stated that, to her knowledge, the eRoom would remain open for the members' use.

Mr. Owens said that he would develop consistent messages and make them available for everyone's use; Mr. Salsberg offered to coordinate with him on this effort.

Ms. Kuenning raised the question of official messaging from the final meeting. Ms. Sylvester responded that though consensus was not reached, much else had gained, in particular the development of relationships. Mr. Salsberg in turn emphasized that the committee should not consider the lack of consensus a failure. He stressed that the committee had been successful in identifying pathways to improve existing methodology and that the creative thinking and teamwork of the group was impressive. Mr. Salsberg felt strongly that the committee was a success.

The committee members provided closing remarks, many thanking their colleagues for tireless effort and expressing pleasure at having served.

The meeting concluded at 5:23.